CL 325 Biomaterials

- Course Objectives:
- Understanding: to define biocompatibility of various materials and classify them according to their suitability for the specific biomedical application
- Apply: to identify the specific biomaterial to be used for a specific tissue or organ replacement
- Analyze: to distinguish the advantages and limitations of specific biomaterials for a specific biomedical application

Course Outcome

After completion of the course the student will be able to:

- *Give examples* of application areas for different types of biomaterials.
- *Apply knowledge* from basic material courses to *identify* material properties that are critical for metallic, polymer and ceramic biomaterials, or their combination.
- *Explain* basic physical, chemical and mechanical processes that may occur on biomaterials in use.
- *Describe* corrosion and degradation processes that occur for different biomaterials and their consequences.
- *Select* proper type of biomaterial for given applications, taking into account function, health risk and economic aspects

Syllabus

MODULE- I

Biomaterials-definition-classification-metal-ceramic-polymers, composites- Source, application, advantage and limitations [6]

MODULE II:

Metals and alloys-Stainless Steels, CO-based alloys, Ti and Ti based alloys and dental metals corrosion and remedy, Ceramics-Aluminum oxides, calcium phosphate, glass-Ceramics, carbon manufacturing and physical properties, deterioration of ceramics [10]

MODULE-III

Polymeric implant materials-polyamides, PE, PP, Polyacrylates, Structure, properties and application of biological materials-proteins, polysaccharides, Structure and property relation of Tissues-Mineralized tissues, collagen rich tissues and elastic tissues [8]

MODULE - IV

Soft tissue replacements-Skin implants-sutures, tissue adhesives, percutaneous devices, artificial skins, maxillofacial implants, ear and eye implants, vascular implants, heart and lung assist devices, artificial kidney dialysis membranes [8]

MODULE V

Hard tissue replacements-long bone repair-wires, pins, screws, fracture plates, tooth implants, joint replacement-knee and hip joint-materials of construction, limitations [8]

Module 1 CL 325

Definition of biomaterials

- A material used to make devices to replace a part or a function of the body in a safe, reliable, economic and physiologically acceptable manner
- Do they differ from biological materials?

Yes, biological materials are essentially obtained from biological (animal or plant) origin e.g. wood, bone etc.

Biomaterials -may or may not be obtained from biological source -metals, polymers, ceramics etc. that are used to make the artificial body parts are termed as biomaterials.

Definition of Biomaterials

- A biomaterial is a synthetic material used to replace part of a living system or to function in intimate contact with living system.

Or

A systemically and pharmacologically inert substance designed for implantation within or incorporation with living systems

contd.

The success of a biomaterial depends on (requirement)-

- Biocompatibility of the materials of construction-blood, tissue etc. -Pharmacological acceptability(nontoxic, non-allergenic, nonimmunogenic, noncarcinogenic etc.)
- Time dependent stability at body condition-thermal, wear, fatigue, chemically inert to body
    - Health condition of the recipient
    - Competency of the surgeon

Adequate mechanical strength-tensile

- Proper density
- Cost efficiency
- Processability
- Reproducibility

Biocompatibility

Can be examined by

- Acute systemic toxicity
- Cytotoxicity
- Hemolysis (rupture of blood cells)
- Intravenous toxicity
- Mutagenicity(induction of permanent transmissible changes in the amount or structure of the genetic material of cells or organisms)
- Oral toxicity
- Pyrogenicity(a fever response)
- Sensitization(the process of becoming sensitive or hypersensitive (as to an antigen)

(Definition) Can be described by

- How biomaterials interact with the human body
- How those interactions determine the clinical success of a medical device

(such as pacemaker, hip replacement or stent)

Definition of biocompatibility

According to ASTM: Comparison of the tissue response produced through the close association of the implanted candidate material to its implant site within the host animal to that tissue response recognised and established as suitable with control materials.

It is the ability of a biomaterial to perform its desired function with respect to a medical therapy, without eliciting any undesirable local or systemic effects in the recipient or beneficiary of that therapy, but generating the most appropriate beneficial cellular or tissue response in that specific situation, and optimising the clinically relevant performance of that therapy(Williams, David F. (2008). "On the mechanisms of biocompatibility". *Biomaterials*. **29** (20)pp-2941. doi:10.1016/j.biomaterials.2008.04.023. PMID 18440630.)

Biocompatibility is the capability of a prosthesis implanted in the body to exist in harmony with tissue without causing deleterious changes (*International dictionary of medicine and biology*, E. L. Becker, S. I. Landau, & A. Manuila, 1986, New York: Wiley.)

Important facts

- Immune response and repair functions in the body are so complicated that it is not adequate to describe the biocompatibility of a single material in relation to a single cell type or tissue.
- Sometimes biocompatibility testing are done by in vitro test that is used in accordance with ISO 10993 (or other similar standards) to determine if a certain material (or rather biomedical product) is biocompatible.
- These tests do not determine the biocompatibility of a material, but they constitute an important step towards the animal testing (in vivo) and finally clinical trials that will determine the biocompatibility of the material in a given application, and thus medical devices such as implants or drug delivery devices.

Guidance on Biocompatibility Assessment

- Data required to assess suitability
- Material characterization-identify the chemical structure of a material and any potential toxicological hazards, residue levels, degradation products
- Information on prior use
- Toxicological data
- Supporting documents
- Details of application: size, shape, form, time in contact
- Chemical breakdown of all materials involved
- A review of all toxicity data on those materials in direct contact of body tissues
- Prior use and details of effects
- Toxicity tests (FDA or ISO)
- Final assessment of all information including toxicological significance

Classification of biomaterials

Materials	Advantages	Disadvantages	Examples
Polymers (nylon, PP, Silicone rubber, polyester, PTFE etc.)	Resilient, Easy to fabricate	Not strong ,deforms with time ,may degrade	Sutures ,blood vessels & other soft tissues, sutures, hip socket, Ear, nose
Metals (Ti and its alloys, Co-Cr alloys, Au, Ag, stainless steels)	Strong, tough, ductile	May corrode, dense, Difficult to fabricate(high temp.)	Joint replacements, dental root implants, pacer and suture wires, bone plates and screws
Ceramics(alumina, zirconia, calcium phosphates including hydroxyapetite, carbon)	Highly biocompatible	Brittle, not resilient, weak in tension	Dental orthopedic implants
Composites(carbon-carbon, wire or fibre reinforced bone cement)	Strong, tailor made	Difficult to make	Bone cement, dental resin

Terms relevant to biomaterials use

- Bioabsorbability-a materials capability to be disolved under body condition with time and be absorbed by the body. These make suitable materials for prosthetics because they can be engineered to dissolve at the same rate as new bone growth.
- Biodegradability: Materials that decompose due to action of biological organisms like bacteria. It may be aerobic or anaerobic degradation.
- Implant-artificial devices made of synthetic materials to replace the natural organ or its function
- Transplantation-replacement of original body organ by another natural organ to restore the function
- Tissue engineering-refers to the growth of a new tissue using living cells guided by the structure of a substrate made of a new material and the substrate is called as scaffold.
- Inflammation-
  localized protective response elicited by injury or destruction of tissues,

that serves to destroy, dilute, or wall off both
the injurious agent and the injured tissue.

Inflammation

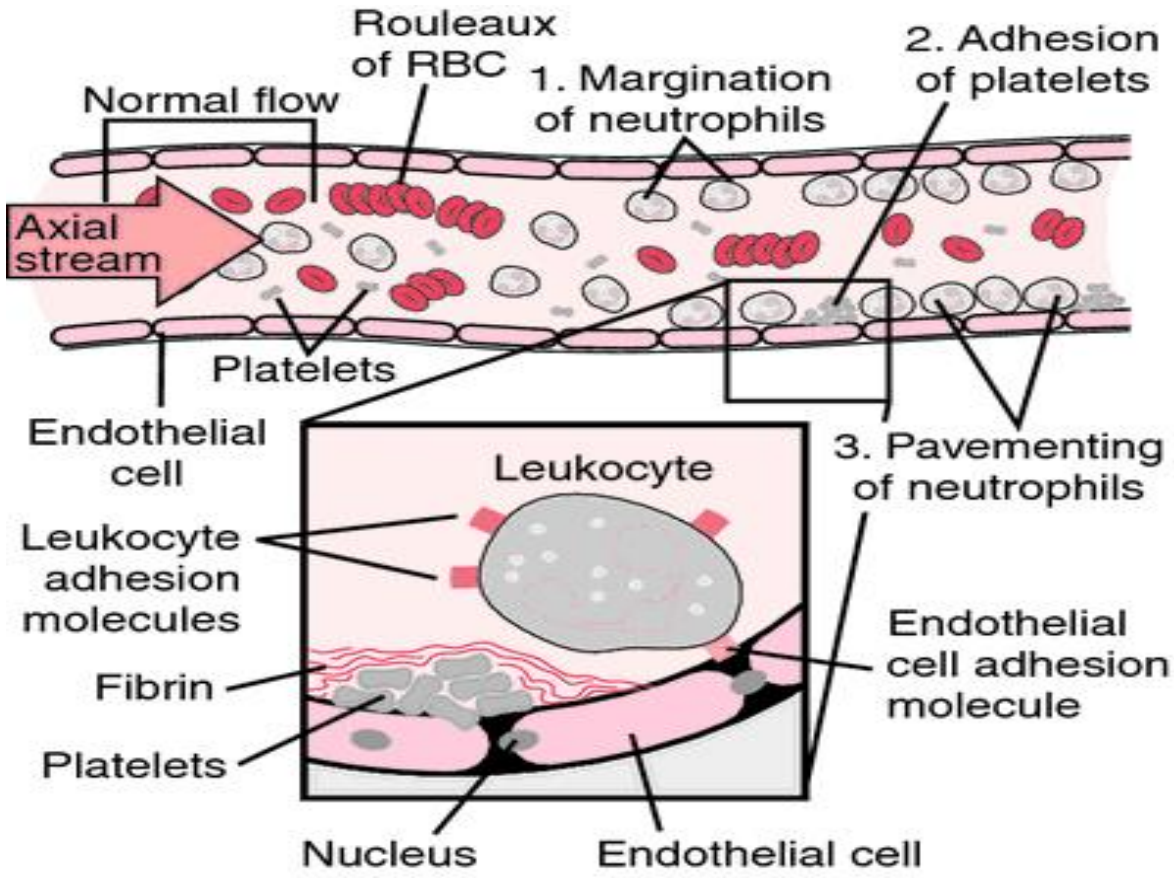
The classic signs of inflammation are *heat, redness, swelling, pain,* and *loss of function.* These are manifestations of physiologic changes that occur during the inflammatory process.

The three major components of this process are (1)changes in the caliber of blood vessels and the rate of blood flow through them (hemodynamic changes); (2) increased capillary permeability; and (3) leukocytic exudation.

Hemodynamic changes -
soon after injury and progress at varying rates, according to the extent of injury. It starts with dilation of the arterioles and the opening of new capillaries and venular beds in the are a. This causes an acceleratedflow of blood, accounting for the signs of heat and redness.

I*ncreased permeability* of the microcirculation,which permits leakage of protein-rich fluid out of small blood vessels and into the extravascular fluid compartment,accounting f or the inflammatory edema.

Leukocytic exudation occurs in the following sequence. First, the **LEUKOCYTES** move to the endot helial lining of the small bloodvessels (*margination*) and line the endothelium in a tightly pack ed formation (*pavementing*). Eventually, these leukocytesmove through the endothelial space s and escape into the extravascular space (*emigration*). Once they are outside the bloodvessel s they are free to move and, by **CHEMOTAXIS**, are drawn to the site of injury. Accumulations of **N EUTROPHILS** and**MACROPHAGES** at the area of inflammation act to neutralize foreign particles by **P HAGOCYTOSIS**.



Cellular changes in **inflammation**.

1, Margination of neutrophils brings these inflammatory cells in close contact with the endo thelium. *2,* Adhesion of plateletsresults in the release of mediators of inflammation and coag ulation. Fibrin strandsare the first signs of clot formation. *3,* Pavementing of leukocytes is me diated byadhesion molecules activated by the mediators of inflammation released fromplatel ets and leukocytes. RBC, red blood cells.

Metals

Advantages:

- High strength-load bearing application
- Bio compatibility-blood, tissue compatibility
- Long term stability in body
- Variety is possible by alloy formation with different compositions
- Can be processed in very fine structure also which have flexible nature combined with high strength

Disadvantages

- Corrosion resistance poor-can give adverse effects to tissue causing inflammation, tissue damage (necrosis)
- Passivation occurs
- Failure after a length of time and rejection/replacement becomes mandatory
- high density
- heavier implant
- processing requires sharp tools and control over heating

Examples

- Stainless steel-hip and knee joints
- Co based alloys- Stems of hip prosthesis, dentistry, plates, screws
- Ti & Ti alloys- All other implants as Co and Stainless steel except screws, plates etc. (due to corrosion)

❖ *Sherman vanadium* steel-for bone fracture plates & screws

Stainless steel

- The first metal developed specifically for human use was “Sherman Vanadium Steel,” which was used to manufacture bone fracture plates and screws. Limitation: inadequate resistance against corrosion
- 18-8sMo stainless steel contains molybdenum to improve corrosion resistance in salt water. This alloy became known as type 316 stainless steel.
- In the 1950s the carbon content of 316 stainless steel was reduced from 0.08 w/o to 0.03 w/o maximum for better corrosion resistance to chloride solution, and it became known as 316L.

Compositions of 316L Stainless Steel Surgical Implants (ASTM, 2000)

Element	Composition (w/o)
Carbon	0.030 max
Manganese	2.00 max
Phosphorus	0.025 max
Sulfur	0.010 max
Silicon	0.75 max
Chromium	17.00–19.00
Nickel	13.00–15.00
Molybdenum	2.25–3.00
Nitrogen	0.10 max
Copper	0.50 max
Fe	Balance

40-45%

(60%-55%)

Types and Composition of Stainless Steels

Chromium is a major component of corrosion-resistant stainless steel.

The *austenitic stainless steels* – especially types 316 and 316L – are most widely used for implants. These are *not* hardenable by heat-treatment but can be hardened by cold-working. This group of stainless steels are nonmagnetic and possess better corrosion resistance than any others. The inclusion of molybdenum enhances resistance to pitting corrosion in salt water.

Properties of Stainless Steel

Depending upon the heat treatment (to obtain softer material)and cold working stainless steel (for greater strength and hardness) wide range of properties are found.

Type 316L may corrode under certain body conditions e.g. highly stressed and oxygen depleted region.

So these are suitable for temporary devices e.g. fracture plates, screws and hip nails.

Manufacturing of Implants Using Stainless Steel

- There are few difficulties in handling the Austenitic stainless steel:
- It cannot be cold worked (as it hardens quickly) without intermediate heat treatment
- During heat treatments chromium carbide formation in the grain boundaries may cause corrosion
- Implants made of austenitic stainless steel cannot be welded
- Possibility of distortion during heat treatment
- Surface oxides formed during heat treatment must be removed by chemical or mechanical means
- The surface is then cleaned, degreased and passivated in nitric acid (ASTM F86)

Practice problem-1

Calculate the amount of volume change when iron is oxidized to FeO ($\rho = 5.95$ g/cm^3). The density of Fe is 7.787 g/cm^3.

Since the molecular weight of Fe is 55.85 g/mol,

$$\frac{55.87 \text{ g/mol}}{7.7 \text{ g/cm}^3} = 7.1 \text{ cm}^3/\text{mol}.$$

The molecular weight of FeO is 71.85 g/mol; hence,

$$\frac{71.85 \text{ g/mol}}{5.95 \text{ g/cm}^3} = 12.08 \text{ cm}^3/\text{mol}.$$

Co-BASED ALLOYS

- These materials are usually referred to as cobalt-chromium alloys.
- There are basically two types:
- one is the CoCrMo alloy, which is usually used to *cast a product, and the other is* CoNiCrMo alloy, which is usually *wrought by (hot) forging.*
- *The castable CoCrMo alloy has* been in use for many decades in dentistry and in making artificial joints.
- The wrought CoNiCrMo alloy has been used for making the stems of prostheses for heavily loaded joints (such as the knee and hip).

Properties of Co-Based Alloys

- One of the most promising wrought Co-based alloys is the CoNiCrMo alloy originally called MP35N (Standard Pressed Steel Co.), which contains approximately 35 w/o Co and Ni each. The alloy has a high degree of corrosion resistance to seawater (containing chloride ions) under stress. Cold-working can increase the strength of the alloy considerably.
- However, there is a considerable difficulty of cold-working, especially when making large devices such as hip joint stems. Only hot-forging can be used to fabricate an implant with the alloy.
- The abrasive wear properties of the wrought CoNiCrMo alloy is similar to the cast Co-CrMo alloy (about 0.14 mm/year in a joint simulation test).
- The superior fatigue and ultimate tensile strength of the wrought CoNiCrMo alloy make it very suitable for applications that require a long service life without fracture or stress fatigue. Such is the case for the stems of the hip joint prostheses.
- The modulus of elasticity for the cobalt-based alloys ranges from 220 to 234 GPa. These values are higher than the moduli of other materials such as stainless steels.

Manufacturing Implants Using Co-Based Alloys

- The CoCrMo alloy is particularly susceptible to the work-hardening so that the normal fabrication procedure used with other metals cannot be employed.
- Lost wax method is employed as below:

1. A wax pattern of the desired component is made.
2. The pattern is coated with a refractory material, first by a thin coating with a slurry (suspension of silica in ethyl silicate solution) followed by complete investing after drying.
3. The wax is melted out in a furnace (100–150^{o}C).
4. The mold is heated to a high temperature, burning out any traces of wax or gas-forming materials.
5. Molten alloy is poured with gravitational or centrifugal force. The mold temperature is about 800–1000^{o}C and the alloy is at 1350–1400^{o}C.

- Controlling the mold temperature will have an effect on the grain size of the final cast; coarse ones are formed at higher temperatures, which will decrease the strength. However, high processing temperatures will result in larger carbide precipitates with greater distances between them, resulting in a less brittle material.

How to calculate the Co atoms release rate?

- Experimental determination of the rate of nickel release from the CoNiCrMo alloy and 316L stainless steel in 37oC Ringer's solution is carried out generally.
- Problem 2:
- Calculate the number of Co atoms released during a year from the femoral head of a hip joint prosthesis made of CoCrMo alloy. Assume that the wear rate is 0.14 mm/yr and that all of the atoms become ionized.
- Assume a nominal diameter of the prosthetic femoral head of 28 mm. The surface area is $A = 4\pi(1.4\ cm)^2 = 24.63\ cm^2$.
- Half of this area is in contact with the socket portion of the joint. Therefore, the volume of wear material is ½ x24.63 cm^2x 0.014 cm/yr = 0.172 cm^3/yr

(Atoms/year) =[0.65 0.172(cm3 /yr)x 8.83 (g/cm3)6.02 x10^{23} (atoms/mol)]/[58.93 (g/mol)]

Since the density of Co is 8.83 g/cm3, and the atomic weight is 58.93, and the alloy is about 65% cobalt,

atoms/yr= 1.0 x 1022 atoms/yr, or 3.2 x 1014 atoms per second

Ti AND Ti-BASED ALLOYS

- Ti was tolerated in cat femurs, as was stainless steel and Vitallium® (CoCrMo alloy). The lightness of titanium (4.5 g/cm3 compared to 7.9 g/cm3 for 316 stainless steel, 8.3 g/cm3 for cast CoCrMo, and 9.2 g/cm3 for wrought CoNiCrMo alloys) and good mechanochemical properties are salient features for implant application.

Compositions of Ti and Ti-Based Alloys

- There are four grades of unalloyed titanium for implant applications
- The impurity contents distinguish them; oxygen, iron and nitrogen should be controlled carefully.
- Oxygen in particular has a great influence on ductility and strength.
- Ti6Al4V- The main alloying elements of the alloy are aluminum(5.5–6.5 w/o) and vanadium (3.5–4.5 w/o).

Chemical Compositions of Ti6Al4V Alloys (ASTM, 2000)

Element	Wrought, forging (F136, F620)	Casting (F1108)	Coating (F1580)
N	0.05	0.05	0.05
C	0.08	0.10	0.08
H	0.012	0.015	0.015
Fe	0.25	0.30	0.30
O	0.13	0.20	0.20
Cu	–	–	0.10
Sn	–	–	0.10
Al	5.5–6.50	5.5–6.75	5.50–6.75
V	3.5–4.5	3.5–4.5	3.50–4.50
Ti		Balance	

Structure and properties of Ti And its alloys

- Titanium is an allotropic material that exists as a hexagonal close-packed structure (α-Ti) up to 882^{o}C and a body-centered cubic structure (β-Ti) above that temperature. The addition of alloying elements to titanium enables it to have a wide range of properties:
- 1.Aluminum tends to stabilize the α phase, that is, increase the transformation temperature from α to β phase
- 2. Vanadium stabilizes the β phase by lowering the temperature of the transformation from α to β.
- The α alloys have single-phase microstructure which promotes good weldability.
- The stabilizing effect of the high aluminum content of these groups of alloys makes for excellent strength characteristics and oxidation resistance at high temperature (300–600oC).
- These alloys cannot be heat-treated for strengthening since they are single phased since the precipitation of the second or third phase increases the strength by precipitation hardening Process.

The mechanical properties of the commercially pure titanium &Ti6Al4V

- The mechanical properties of the commercially pure titanium, Ti6Al4V, are given in next page. The modulus of elasticity of these materials is about 110 GPa, which is half the value of Co-based alloys.
- The higher impurity content leads to higher strength and reduced ductility.
- The strength of the Ti alloys is similar to 316 stainless steel or the Co-based alloys. When compared by specific strength (strength per density), the titanium alloy excels any other implant materials.
- Titanium, nevertheless, has poor shear strength, making it less desirable for bone screws, plates, and similar applications.
- Titanium derives its resistance to corrosion by the formation of a solid oxide layer. Under in vivo conditions the oxide (TiO_2) is the only stable reaction product. The oxide layer forms a thin adherent film and passivates the material.

Mechanical Properties of Ti6Al4V (ASTM, 2000)

Properties	Wrought (F136)	Casting (F1108)
Tensile strength ksi (MPa)	125 (860)	125 (860)
Yield strength (0.2% offset) ksi (MPa)	115 (795)	110 (758)
Elongation (%)	10 min	8 min
Reduction of area (%)	20 min	14 min

Mechanical Properties of Pure Titanium (F67, 1992) (ASTM, 2000)

Properties	Grade 1	Grade 2	Grade 3	Grade 4
Tensile strength ksi (MPa)	35 (240)	50 (345)	65 (450)	80 (550)
Yield strength (0.2% offset) ksi (MPa)	25 (170)	40 (275)	55 (380)	70 (485)
Elongation (%)	24	20	18	15
Reduction of area(%)	30	30	25	25

1 ksi = 1,000 psi, 1 psi = 6,895 Pa

Manufacture of Implants

- Titanium is very reactive at high temperature and burns readily in the presence of oxygen.
- It therefore requires an inert atmosphere for high-temperature processing or is processed by vacuum melting.
- Oxygen diffuses readily in titanium, and the dissolved oxygen embrittles the metal. As a result any hot-working or forging operation should be carried out below 925^{o}C.
- Machining at room temperature is not the solution to all the problems since the material also tends to gall or seize the cutting tools. Very sharp tools with slow speeds and large feeds are used to minimize this effect. Electrochemical machining is an attractive means.

DENTAL METALS

- Dental Amalgam
- An *amalgam is an alloy in which one of the component metals is mercury.*
- *The rationale for* using amalgam as a tooth filling material is that since mercury is a liquid at room temperature it can react with other metals such as silver and tin and form a plastic mass that can be packed into the cavity, and which hardens (sets) with time.
- To fill a cavity the dentist mixes solid alloy, supplied in particulate form, with mercury in a mechanical triturator. The resulting material is readily deformable and is then packed into the prepared cavity.
- The reaction during setting is thought to be:

$$\gamma + Hg \longleftrightarrow \gamma + \gamma_1 + \gamma_2$$

in which the γ phase is Ag_3Sn, the γ_1 phase is Ag_2Hg_3, and the γ_2 phase is Sn_7Hg,

Dental amalgams typically contain 45 to 55% mercury, 35 to 45% silver, and about 15% tin, when fully set

- The strength of the restoration increases during the setting process, so that the amalgam has attained one quarter of its final strength after one hour, and almost all of its final strength after one day.

Gold

- Gold and gold alloys are useful metals in dentistry as a result of their durability, stability, and corrosion resistance
- Gold fillings are introduced by two methods: casting and malleting.

Gold- *Cast* restorations

- *Cast* restorations are made by taking a wax impression of the prepared cavity, making a mold from this impression in a material such as gypsum silica, which tolerates high temperature, and casting molten gold in the mold.
- Gold *alloys are used for cast restorations, since they have mechanical properties superior to* those of pure gold
- Copper, alloyed with gold, significantly increases its strength. Platinum also improves strength, but no more than about 4% can be added, or the melting point of the alloy is elevated excessively. Silver compensates for the color of copper.
- A small amount of zinc may be added to lower the melting point and to scavenge oxides formed during melting. Gold alloys of different composition are available. Softer alloys containing more than 83% gold are used for inlays, which are not subjected to much stress.
- Harder alloys containing less gold are chosen for crowns and cusps, which are more heavily stressed.

Gold- *Malleted restorations*

- *Malleted restorations are built up in the cavity from layers of pure gold foil.*
- The foils are degassed before use, and the layers are welded together by pressure at room temperature
- The pure gold is relatively soft, so this type of restoration is limited to areas not subjected to much stress.
- In this type of welding the metal layers are joined by thermal diffusion of atoms from one layer to another. Since intimate contact is required in this procedure, it is particularly important to avoid contamination.

Nickel-Titanium Alloys

The SME can be generally related to a diffusionless martensitic phase transformation that is also thermoelastic in nature, the thermoelasticity being attributed to ordering in the parent and martensitic phases.

The nickel-titanium alloys show an unusual property in that after the metal is deformed they can snap back to their previous shape following heating. This phenomenon is called the *shape memory effect. The shape memory effect (SME) of Ni-Ti alloy was first observed by Buehler* and Wiley at the U.S. Naval Ordnance Laboratory (NOL).

- The equiatomic Ni-Ti alloy (Nitinol R) exhibits an exceptional SME near room temperature: if it is plastically deformed below the transformation temperature, it reverts back to its original shape as the temperature is raised.
- Shape memory alloys are used in orthodontic dental arch wires. They also are used in arterial blood vessel stents, and may be used in vena cava filters, intracranial aneurysm clips, and orthopedic implants. On a more speculative level, they might find use in contractile artificial muscles for an artificial heart.

Salient Features

The thermoelastic martensitic transformation exhibits the following general characteristics:

1. Martensite formation can be initiated by cooling the material below *Ms, defined* as the temperature at which the martensitic transformation begins. Martensite formation can also be initiated by applying a mechanical stress at a temperature above *Ms.*
2. *Ms and As (temperature at which the reverse austenitic transformation begins* upon heating) temperatures can be increased by applying stresses below the yield point; the increase is proportional to the applied stress.
3. The material is more resilient than most metals.
4. The transformation is reversible.

Properties of Ni-Ti Alloys

- A widely known Ni-Ti alloy is 55-Nitinol (55 weight % (w/o) or 50 atomic % (a/o) Ni), which has a single phase and “mechanical memory” plus other properties — for example, high acoustic damping, direct conversion of heat energy into mechanical energy, good fatigue properties, and low temperature ductility.
- Deviation from the 55-Nitinol (near stoichiometric Ni-Ti) in the Ni-rich direction yields a second group of alloys that are also completely nonmagnetic but differ from 55- Nitinol in their capability of being thermally hardened to higher hardness levels. Shape recovery capability decreases and heat-treatability increases rapidly as Ni content approaches 60w/o.
- The efficiency of 55-Nitinol shape recovery can be controlled by changing the final annealing temperatures during preparation of the alloy device. For the most efficient recovery,the shape is fixed by constraining the specimen in a desired configuration and heating to between 482 and 510^{o}C.
- Both 55- and 60-Nitinols have relatively low moduli of elasticity and can be tougher and more resilient than stainless steel, Ni-Cr, or Co-Cr based alloys.
- The Ni-Ti alloys also exhibit good biocompatibility and corrosion resistance in vivo.

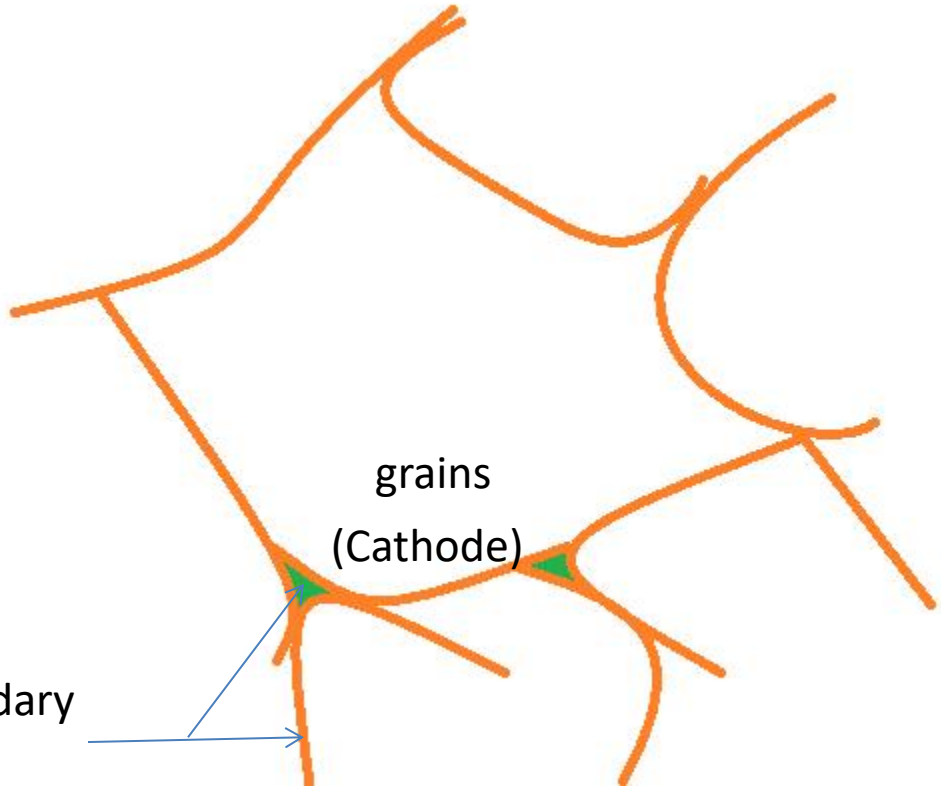
Corrosion in metal implants

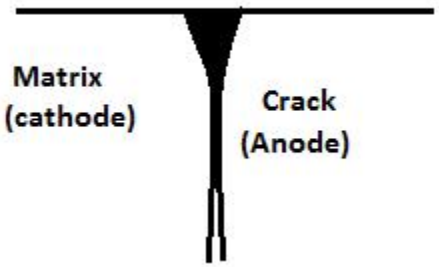
- If two dissimilar metals are present in the same environment, the one that is most negative in the galvanic series will become the anode.
- Galvanic corrosion can be more rapid than the corrosion of a single metal.
- Implantation with alloys is therefore to be avoided.
- Galvanic corrosion can be possible in single metal if there is inhomogeneity in the metal or its environment

Corrosion Vs. Biocompatibility

- Corrosion is the unwanted chemical reaction of a metal with its environment, resulting in continued degradation to oxides, hydroxides, or other compounds.
- Tissue fluid in the human body contains water, dissolved oxygen, proteins, and various ions such as chloride and hydroxide.
- As a result, the human body presents a very aggressive environment to metals used for implantation.
- Corrosion resistance of a metallic implant material is consequently an important aspect of its biocompatibility
- The lowest free energy state of many metals in an oxygenated and hydrated environment is that of the *oxide.*
- *Corrosion occurs when metal atoms become ionized and go into solution, or* combine with oxygen or other species in solution to form a compound that flakes off or dissolves.

Micro-corrosion Cells in single metals





Factors responsible are

- Repetitive deformation in metals in corrosive environment e.g. salts, ions etc. in body fluid, fatigue testing, rubbing off passive layer, pitting cause local corrosion,
- Grain boundaries and crevices in the area of contact of a screw with bone plates.

Chemical reactions during corrosion in metal implants

- In the body an external electrical driving source may be present in the form of a cardiac pacemaker, or an electrode used to stimulate bone growth. At the anode, or positive electrode, the metal oxidizes. The following reactions involving a metal M may occur:

$$M \Leftrightarrow M^{+n} + ne^{-}.$$

At Cathode following reactions occur:

$$M^{+n} + ne^{-} \Leftrightarrow M,$$

$$M^{++} + OH^{-} + e^{-} \Leftrightarrow MOH,$$

$$2H_3O^{+} + 2e^{-} \Leftrightarrow H_2O + 2H_2O,$$

$$\tfrac{1}{2}O_2 + H_2O + 2e^{-} \Leftrightarrow 2OH^{-}.$$

If two dissimilar metals are present in the same environment, the one that is most negative in the *galvanic series will become the anode, and bimetallic (or galvanic) corrosion will occur.*
Galvanic corrosion can be much more rapid than the corrosion of a single metal. Consequently, implantation of dissimilar metals (mixed metals) is to be avoided.

Ceramics

- Alumina-
- Zirconia-
- Calcium phosphate
- Titanium oxide
- Porous Calcium Aluminate
- Tri-calcium phosphate
- Glass- ceramics

Comparison of properties of metals with ceramics

Metals

- Mechanical strength (Modulus of elasticity GPa) –steel(230GPa),Co-alloys(220-234), Ti alloys(110) and Tantalum(27550)
- Use-hard tissue replacement, total hip replacement

Ceramics

- Mechanical strength(Modulus of elasticityGPa)–CP(40-117), ZrO_2(210), $Al_2 O_3$(380)
- Use-cementing for bone implant fixation

CALCIUM PHOSPHATE

- Calcium phosphate has been used to make artificial bone.
- Recently, this material has been synthesized and used for manufacturing various forms of implant as well as for solid or porous coatings on other implants.
- There are mono-, di-, tri-, and tetra-calcium phosphates, in addition to the hydroxyapatite and β-whitlockite, which have ratios of 5/3 and 3/2 for calcium and phosphorus (Ca/P), respectively.
- Hydroxyapatite acts as a reinforcement in hard tissues and is responsible for the stiffness of bone, dentin, and enamel
- The mineral part of bone and teeth is made of a crystalline form of calcium phosphate similar to hydroxyapatite [$Ca_{10}(PO_4)_6(OH)_2$]
- The ideal Ca/P ratio of hydroxyapatite is 10/6 and the calculated density is 3.219 g/cm3.

Properties of Calcium Phosphates (Hydroxyapatite) in comparison to enamel

- Hard tissues such as bone, dentin, and dental enamel are natural composites that contain hydroxyapatite (or a similar mineral) as well as protein, other organic materials, and water. Enamel is the stiffest hard tissue with an elastic modulus of 74 GPa, and it contains the most mineral. Dentin (E = 21GPa) and compact bone (E = 12~18 GPa) contain comparatively less mineral.
- The Poisson's ratio for the mineral or synthetic hydroxyapatite is about 0.27, which is close to that of bone (≈ 0.3).

Physical Properties of Synthetic Calcium Phosphates

Properties	Values
Elastic modulus (GPa)	40–117
Compressive strength (MPa)	294
Bending strength (MPa)	147
Hardness (Vickers, GPa)	3.43
Poisson's ratio	0.27
Density (theoretical, g/cm^3)	3.16

Synthetic Polycrystalline hydroxyapatite has a high elastic modulus (40–117 GPa) which is close to that of enamel.
Hydroxyapatite is excellent biocompatible material.
It appears to form a direct chemical bond with hard tissues.

Manufacture of Calcium Phosphates (Hydroxyapatite)

- Mainly it is obtained from precipitate of aqueous solution of $Ca(NO_3)_2$ and NaH_2PO_4. Precipitates are filtered and dried to form a fine particle powder.
- After calcination for about 3 hours at 900ºC to promote crystallization, the powder is pressed into final form and sintered at about 1050–1200ºC for 3 hours.
- Above 1250ºC the hydroxyapatite shows a second phase precipitation along the grain boundaries.

GLASS-CERAMICS

- Glass-ceramics are polycrystalline ceramics made by controlled crystallization of glasses.
- They were originally developed by S.D. Stookey of Corning Glass Works in the early 1960s.
- They were first utilized in photosensitive glasses in which small amounts of copper, silver and gold are precipitated by ultraviolet light irradiation.
- These metallic precipitates help to nucleate and crystallize the glass into a fine grained ceramic which possess excellent mechanical and thermal properties.
- Bioglass® and Ceravital® are two glass-ceramics developed for implants.

Properties and application of glass ceramics

- The glass-ceramics developed for implantation are SiO_2–CaO–Na_2O–P_2O_5 and Li_2O–ZnO–SiO_2 systems.
- Glass-ceramics have several desirable properties compared to glasses and ceramics.
- The thermal coefficient of expansion is very low, typically 10–7 to 10–5 per degree C, and in some cases it can be made even negative.
- Due to the controlled grain size and improved resistance to surface damage, the tensile strength of these materials can be increased by at least a factor of two, from about 100 to 200 MPa.
- The resistance to scratching and abrasion are close to that of sapphire.
- The main drawback of the glass-ceramic is its brittleness, as is the case with other glasses and ceramics.
- Additionally, due to restrictions on the composition for biocompatibility (or osteogenicity),mechanical strength cannot be substantially improved as for other glass-ceramics.
- Therefore, they cannot be used for making major load-bearing implants such as joint implants.
- However, they can be used as fillers for bone cement, dental restorative composites, and coating material.

Aluminum oxides

- Alpha-alumina (α-Al_2O_3) has a hexagonal close-packed structure (a = 0.4758 nm and c =1.2991 nm).
- Natural alumina is known as sapphire or ruby (depending on the types of impurities that give rise to color).
- The single-crystal form of alumina has been used successfully to make implants.
- The high hardness is accompanied by low friction and wear; these are major advantages of using the alumina as joint replacement material in spite of its brittleness.

Zirconia

- Zirconia has many salient features in comparison with alumina.
- The biocompatibility of zirconia is about the same as alumina ceramic, but its tribological properties are quite different.
- The friction coefficient also showed a lower value for the zirconia (0.028–0.082) than alumina (0.044–0.115) or 316L stainless steel (0.061–0.156).
- One reason for the excellent wear and friction characteristic of the zirconia is attributed to the fact that zirconia has less porosity.
- Some researchers evaluated the use of zirconia for a hemiarthroplasty femoral head implant and found it suitable due to its low friction with articular cartilage and its excellent biocompatibility.

CARBONS

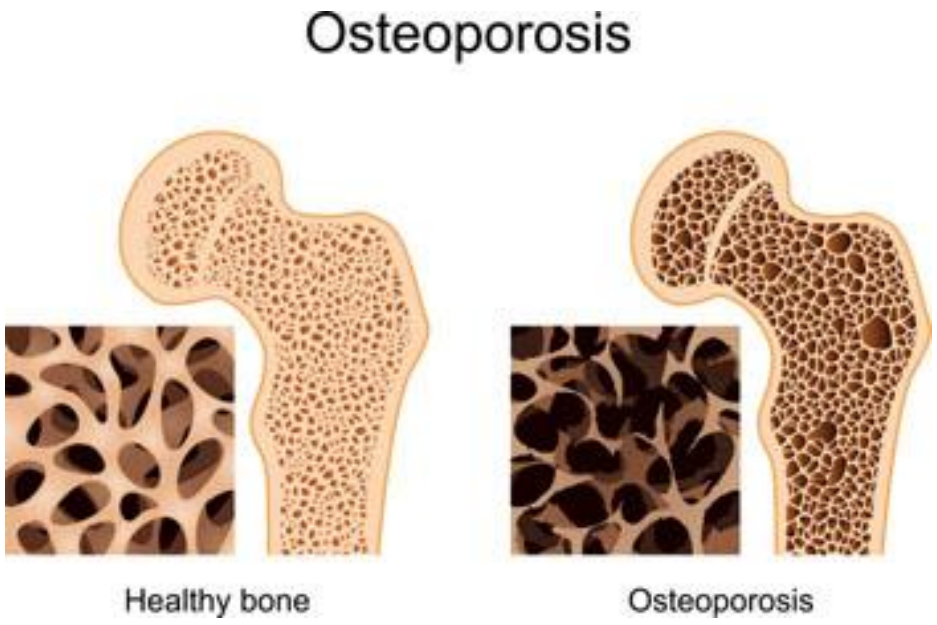
- Pyrolytic carbon is widely utilized for implant fabrication; it is normally used as a surface coating on such medical devices as surgical knives, scissors, and articulating surfaces of joint implants
- The mechanical properties of carbon, especially pyrolytic carbon, are largely dependent on density.
- The increased mechanical properties are directly related to the increased density, which indicates the properties depend mainly on the aggregate structure of the material

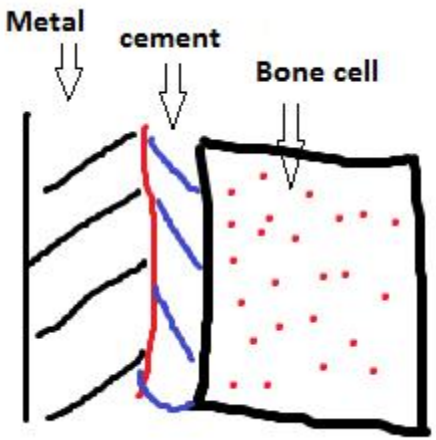
Composites

- **The word ""composite"" refers to the combination, on a macroscopic scale, of two or more materials, different for composition, morphology and general physical properties.**
- **Most human tissues such as bones, tendons, skin, ligaments, teeth, etc., are composites, made up of single constituents whose amount, distribution, morphology and properties determine the final behavior of the resulting tissue or organ.**
- **Man-made composites can, to some extent, be used to make prostheses able to mimic these biological tissues, to match their mechanical behavior and to restore the mechanical functions of the damaged tissue.**
- **Biocomposite** (latin for 'grown by sun') is a composite material formed by a matrix (resin) and a reinforcement of natural fibers. These kind of materials often mimic the structure of the living materials involved in the process keeping the strengthening properties of the matrix that was used, but always providing biocompatibility.

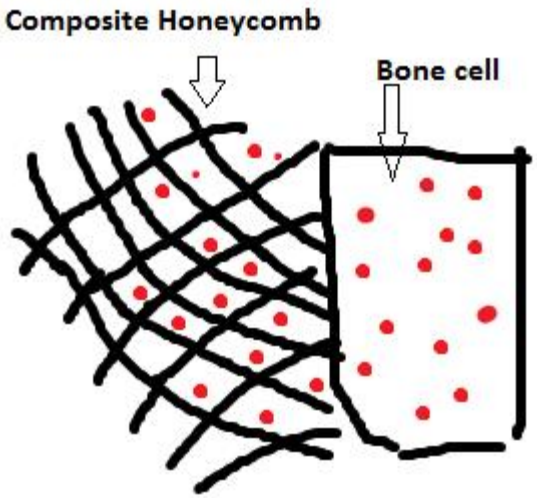
Why do we require composites?

- Failure of orthopedic surgery-allergic reaction , wear and loss of material, Bone weakening due to stress on metal only, revision surgery costlier by 41% than first, more complicated than the first and patient has to stay longer at hospital, 30% patients require revision after 15 yrs
- Bone is porous-Composite biomaterial preserve the strength of bone in contrast to metal implant.





Metal Implant to bone adhesion through cement

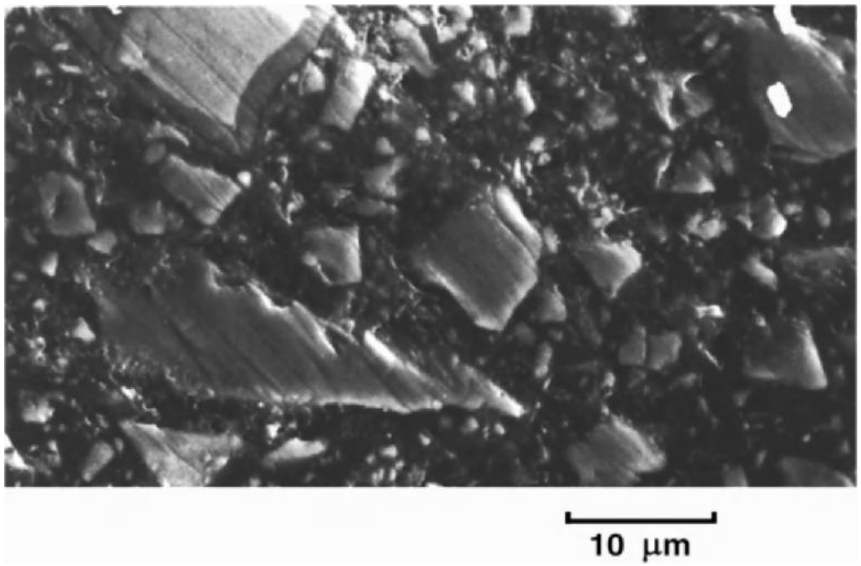


Composite to bone adhesion through tissue ingrowth

Application of composites

- Acrylic resin & silicate used for anterior teeth –cosmetic reason-

poor mechanical strength-short life & clinical failure

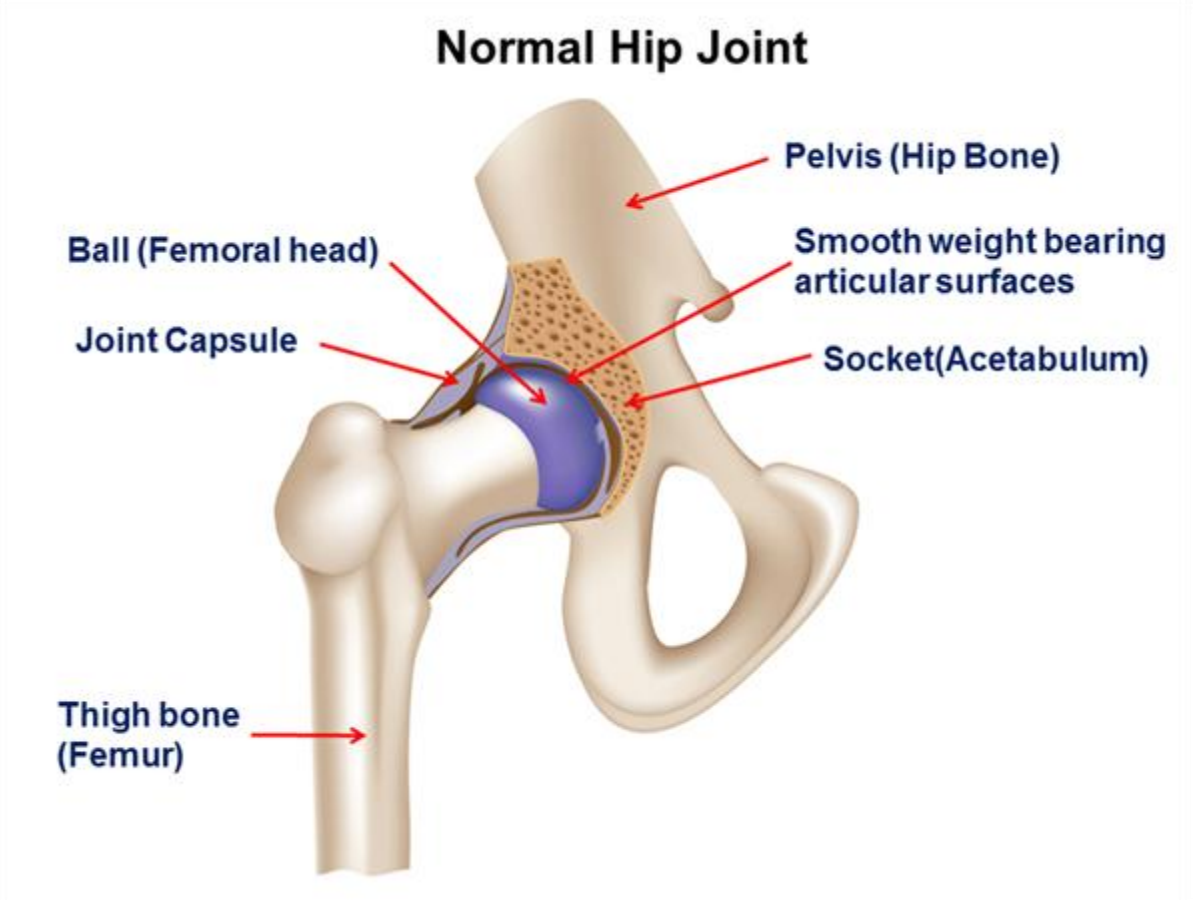


50% by volume filler: barium glass and colloidal silica.

Hip Replacements

- A damaged hip joint is surgically replaced with an artificial implant.
- Patients require differing degrees of replacements, such as total or partial implants, and new hips are made from plastic, ceramic and metal materials.

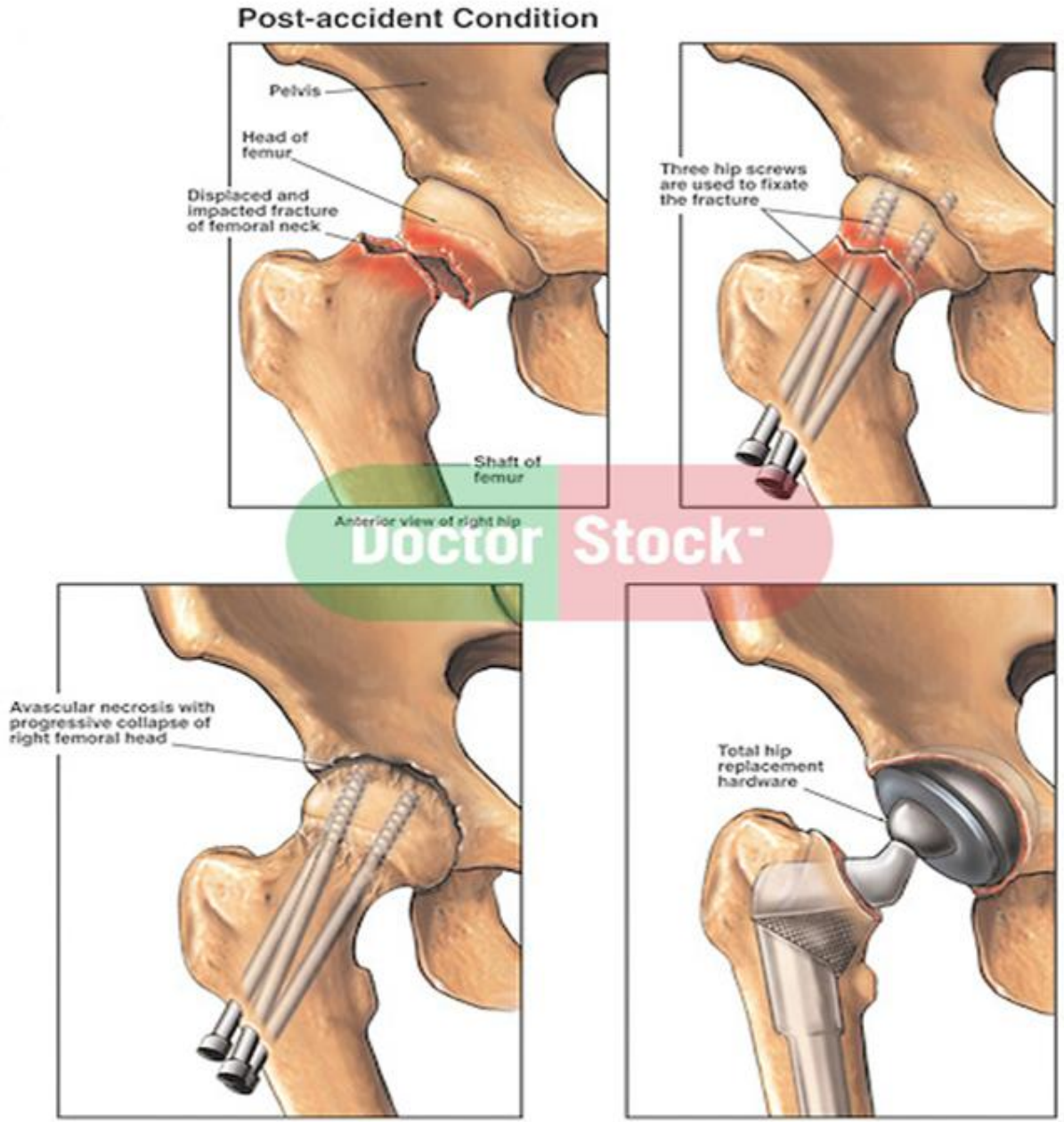
1. Total Hip Replacement (THR)
2. Partial Hip Replacement
3. Hip Resurfacing

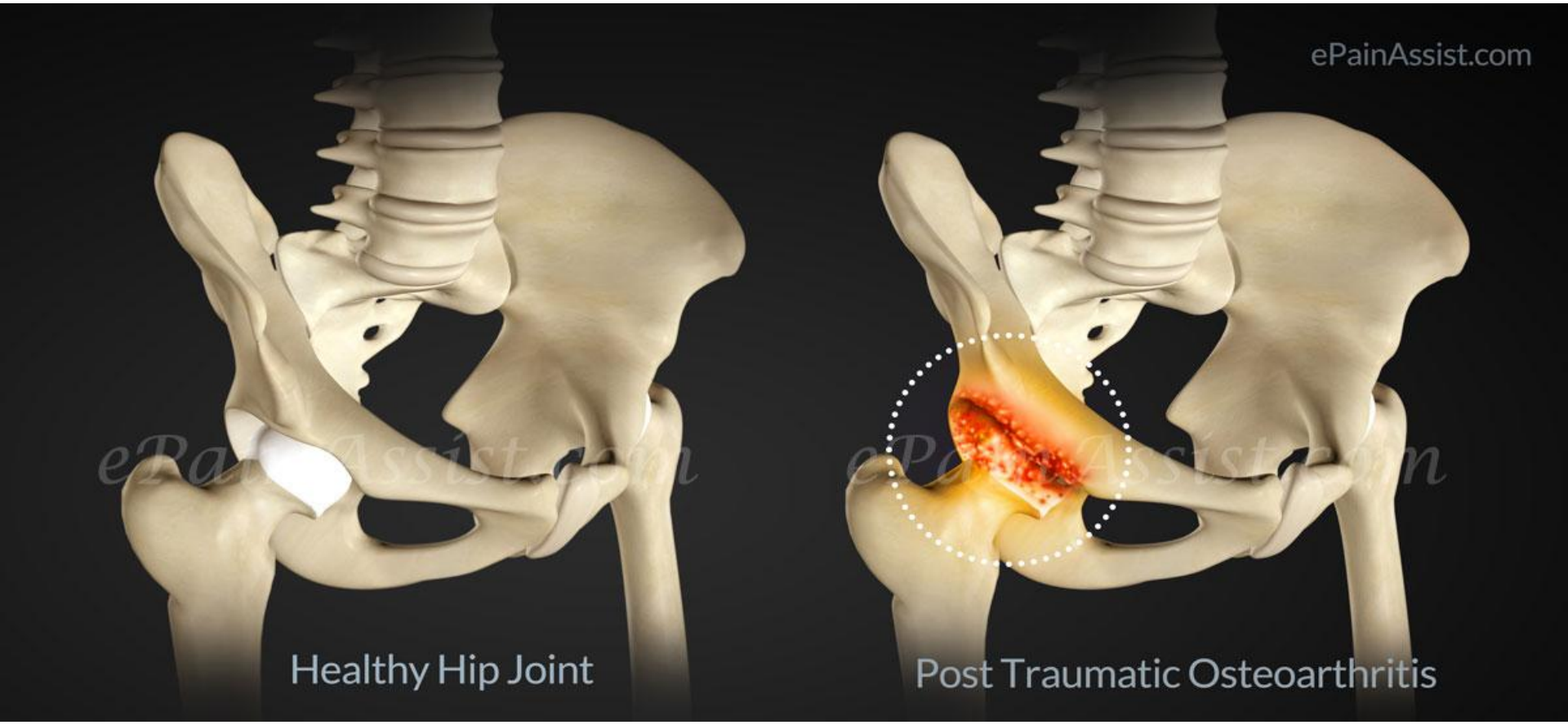


When do we require hip joint replacement?

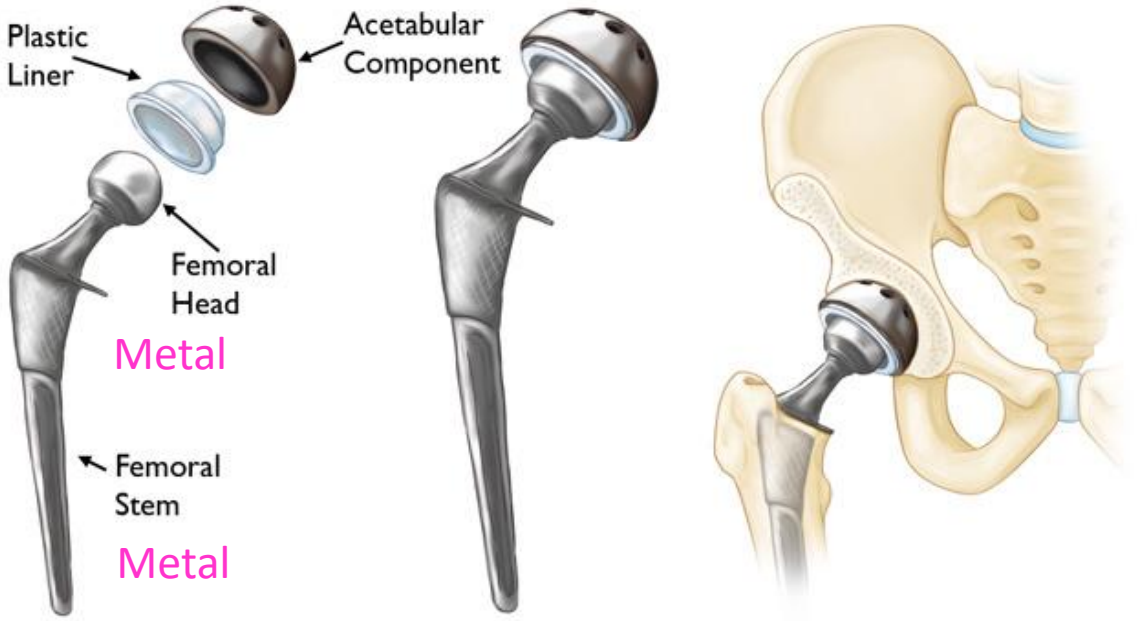
Osteoarthritis in the hip is a condition where the surface(cartilage) of the joint of the hip gradually wear away resulting in inflammation. This may happen because of a specific previous injury and due to over repetitive forces on the hip, which goes beyond the tolerance limit of the hip after a certain period of time.

Traumatic Hip Fracture (Broken Hip) with Surgical Fixation and Total Joint Replacement (Arthroplasty).




ePainAssist.com
Healthy Hip Joint
Post Traumatic Osteoarthritis

UHMHDPE



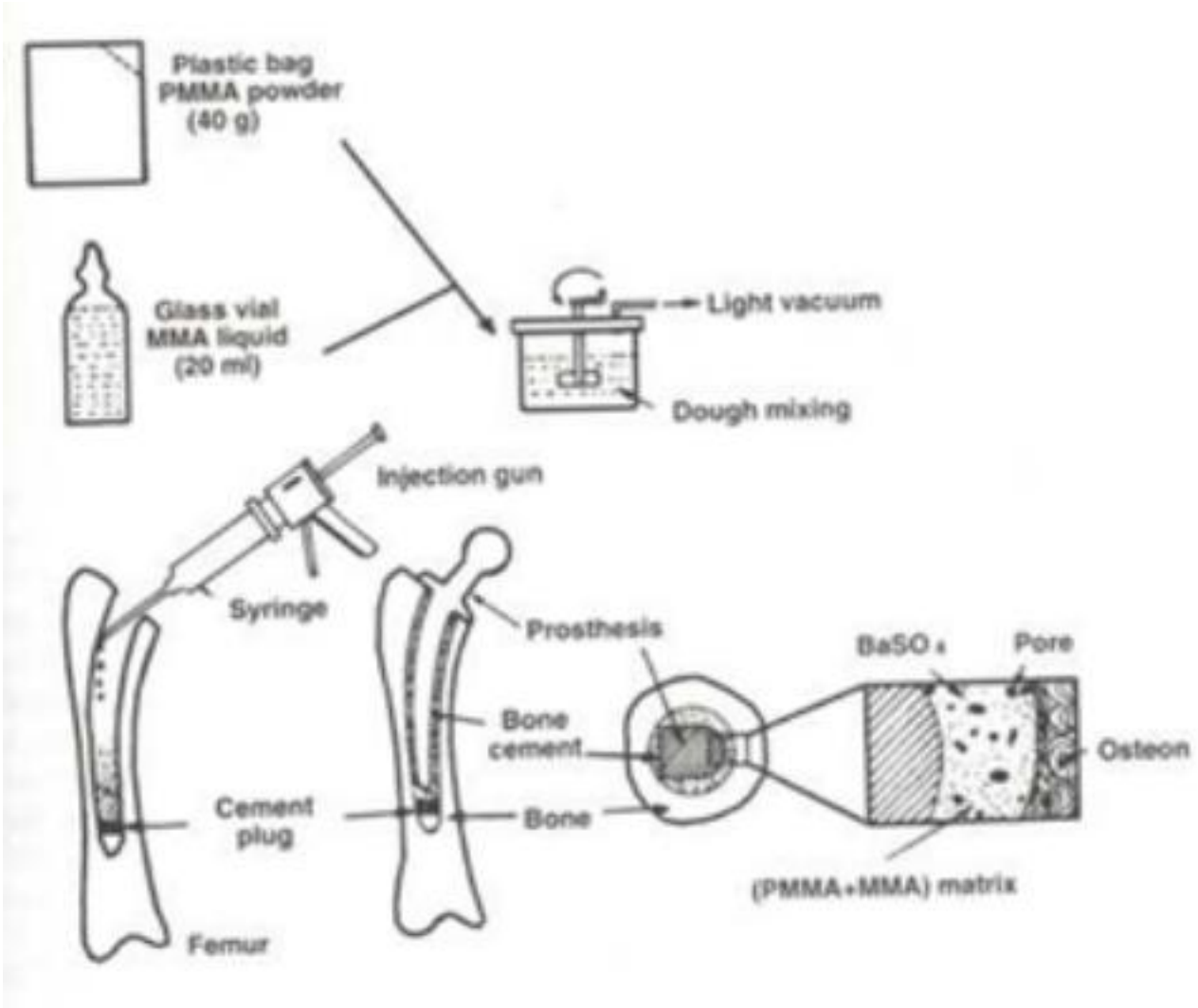
- Marius Smith-Petersen, an American surgeon made the first arthroplasty mold in 1925, and went on to create the first total hip replacement (THR), made with stainless steel.
- In 2015, U.S. surgeons performed an estimated 378,000 total hip replacements, and by 2020, that number will grow to more than 510,000, according to Medscape.
- The average cost of a total hip replacement is about $30,000
- The surgery takes about 1-2 hours, plus another 1-2 hours of prep time before hand. The patient's size and overall health may also influence these estimates. After the surgery patients will stay a few days in the hospital and have to take blood thinners to prevent blood clots.

Dr. D. Charnley used bone cement for fixation.

Salient Features of Total Hip replacement

- The diseased femoral head is cut off and the medullary canal of the femur is drilled and reamed to prepare it for the stem of the prosthesis.
- The cartilage of the acetabulum is also reamed.
- PMMA bone cement is prepared from polymer powder and monomer liquid till the correct dough consistency is reached-it is packed into the medullary canal of the femur and the femoral stem is inserted.
- Replace the head of the femur with a ball and replace the socket with an artificial cup.

Procedure of hip joint replacement



Biomaterials-an Introduction by J.B. PARK

Salient features of hip replacement

- Special bone cement usually holds hip implants in place
- Cementless fixation technique-specially textured surface that encourages the bone to grow onto the implant and secure it in place.
- A hybrid total hip replacement uses a combination of both, implanting the cup without cement and setting the stem in place with cement.
- Traditional Charnley type hip replacement used UHMWHDPE acetabular cup and metallic (stainless steel 316L, Co-Cr and Ti based alloys) femoral head and stem
- In original Charnley prosthesis PTFE was used in place of PE

Partial hip replacement & resurfacing

- Either acetabulum or femoral head can be replaced or hip fracture in the neck of femor can be rectified by the same procedure as earlier.

Hip resurfacing is done to avoid bone loss due to errosion.

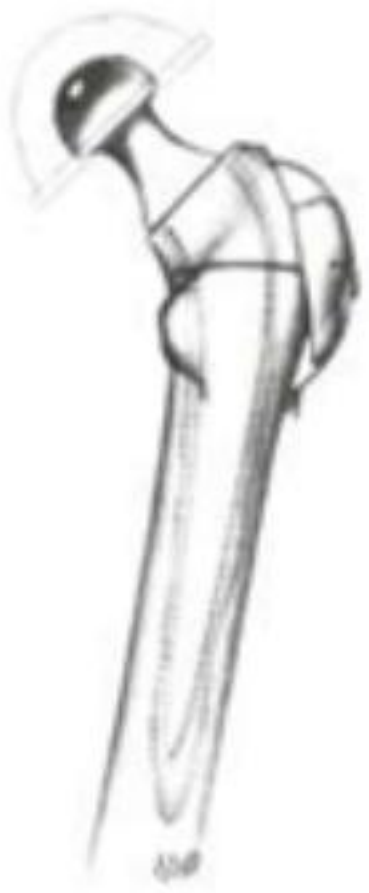
It replaces the socket with an artificial cup and resurfaces the head of femur by cementing process.

- This component has a short stem inserted into the neck of the femur.
- Hip resurfacing often improves symptoms of arthritis.

Hip Implant Devices

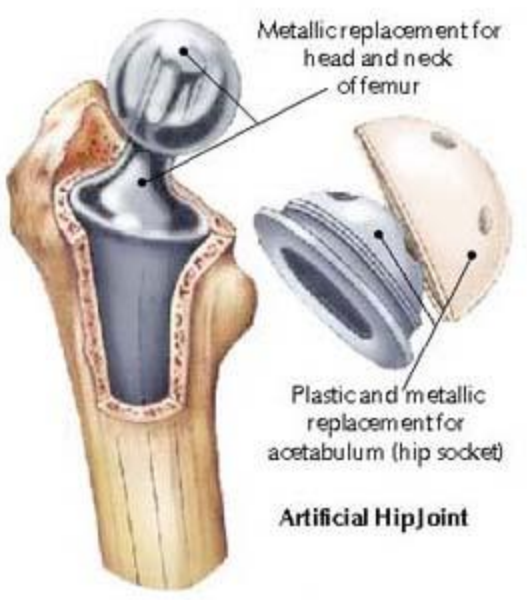
- Metal –on –metal
- Metal on Plastic
- Ceramics-on -metal
- Ceramics on Plastic
- Ceramics on Ceramics

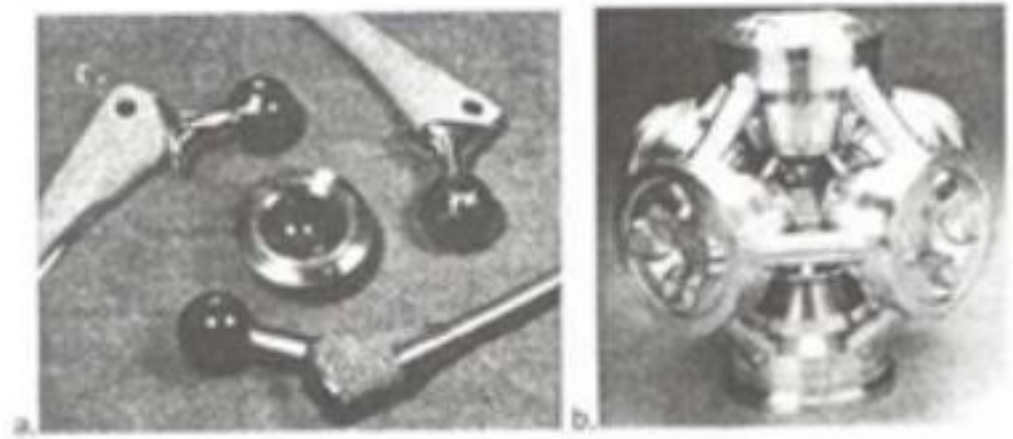
Charnley Hip Prosthesis-
Polymeric cup and femoral stem with small diameter head claimed to be low friction with less contact surface



Difficulties

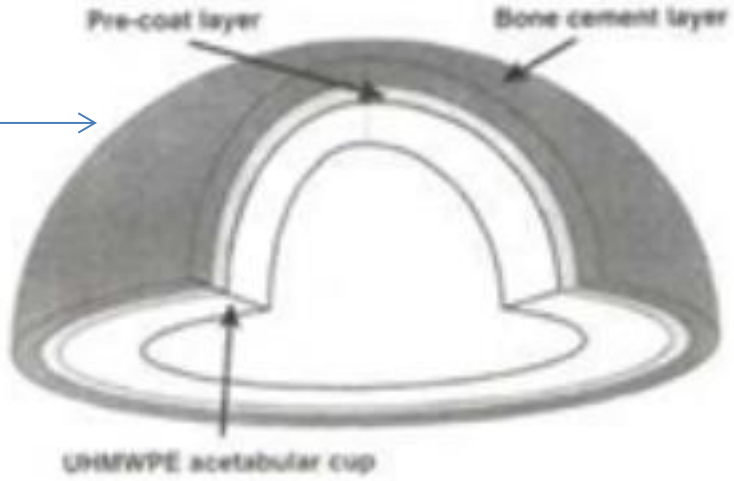
- Fixation of implants-due to the fact that the implant has an interface with the cancellous bone which is much weaker than compact bone.



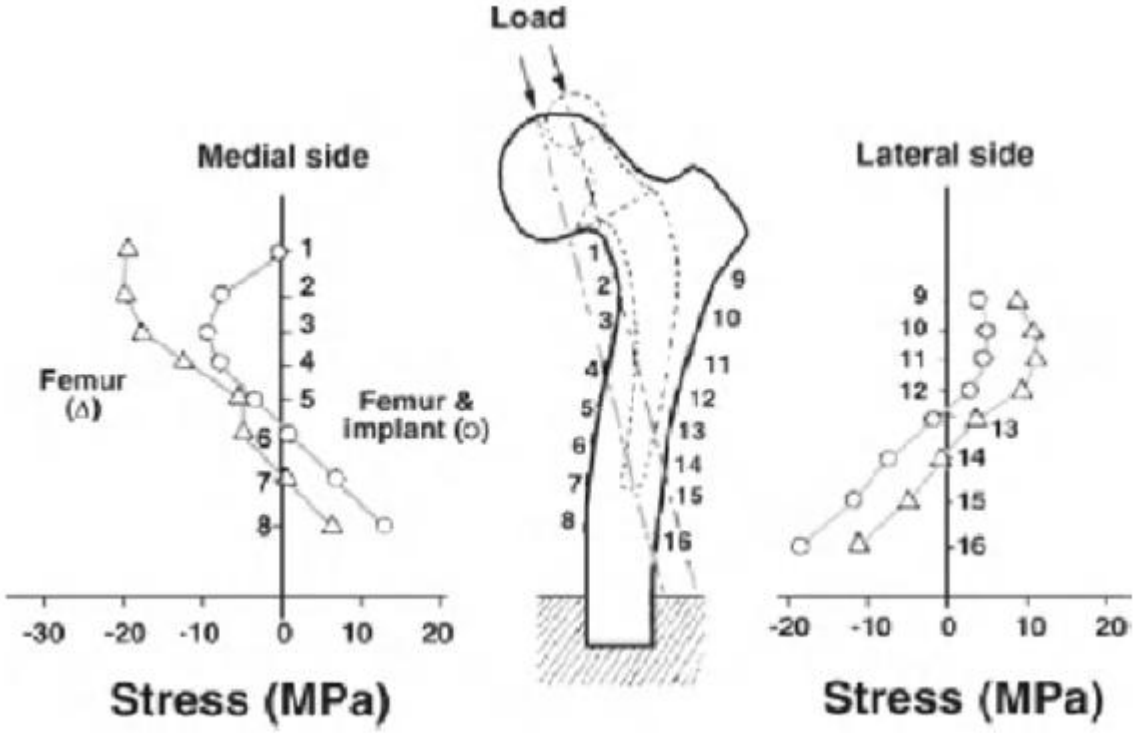


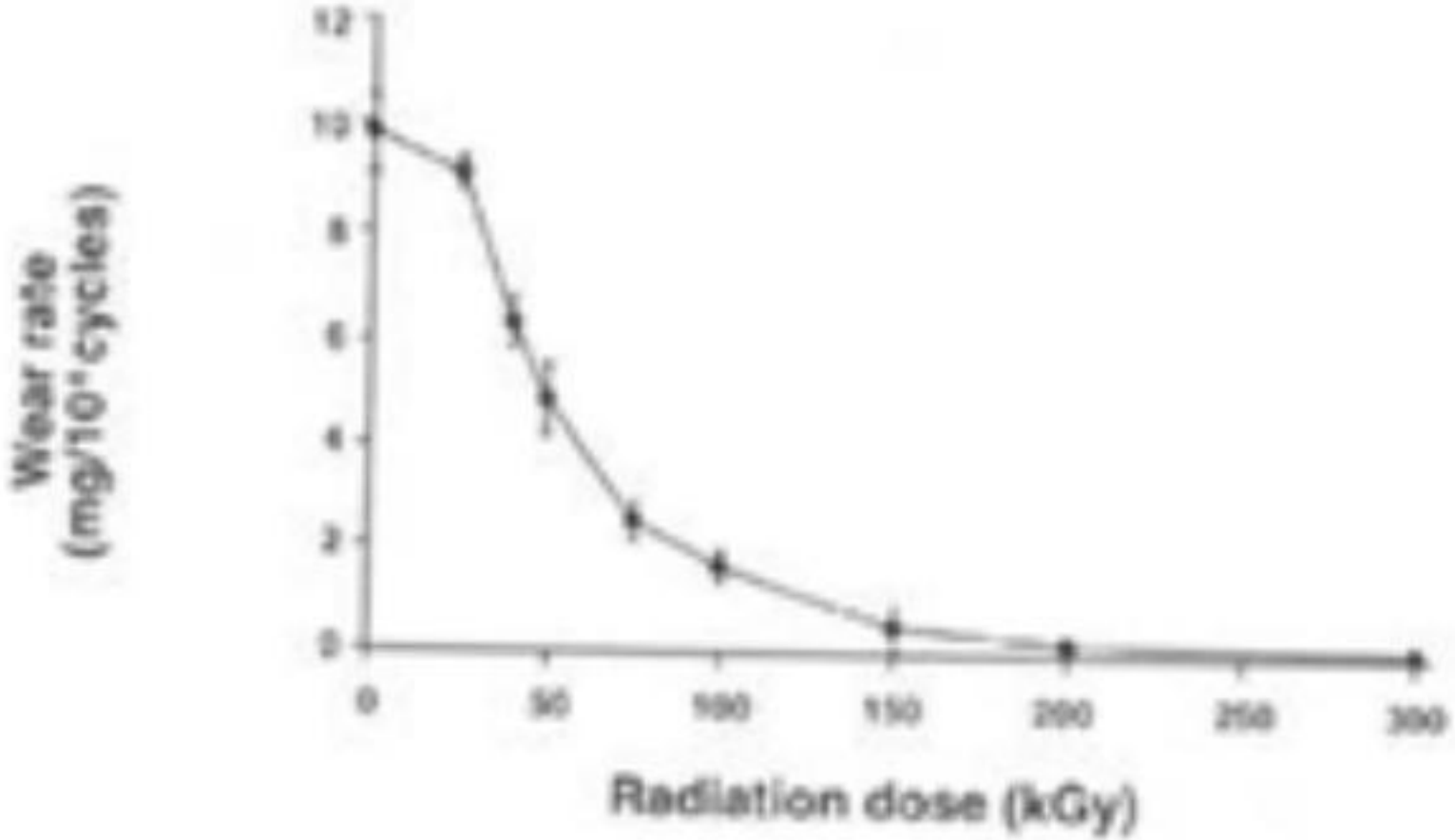
Coating surfaces of head and cup with compact diamond

Pre-coating all-poly acetabular cup outer surface with bone cement layer combined with X-linked UHMWPE



Stresses on the surface of the femoral stem by a load of 4000N.

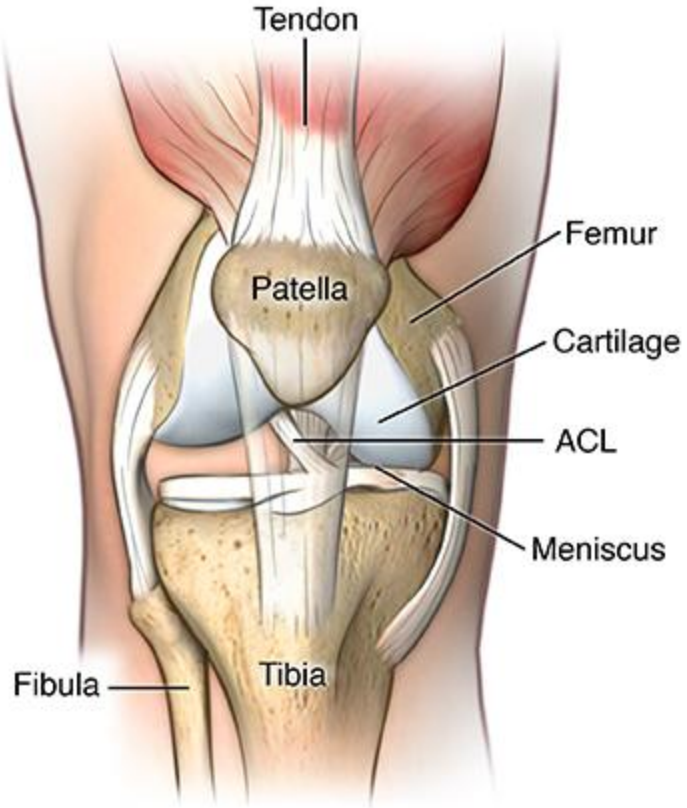




Wear rate Vs. Degree of X-links(radiation dose)

knee joint replacement

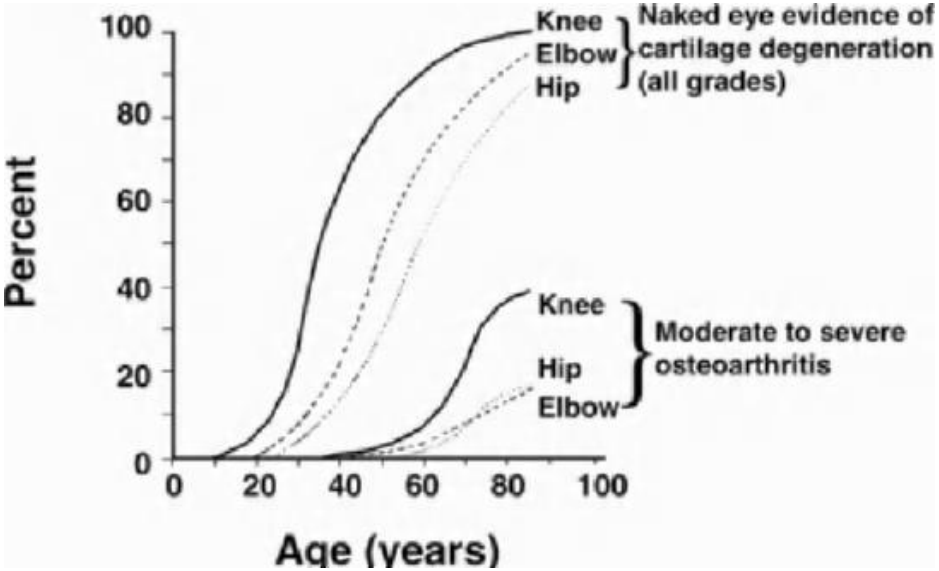
- Damage from arthritis is the most common reason for knee joint replacement. This includes both osteoarthritis and rheumatoid arthritis.
- The prosthesis is made of metal alloys and polymers



Normal knee

The ends of the bone are covered with a smooth, glistening layer called articular cartilage. The articular cartilage is what allows the bones to glide smoothly with less resistance than ice sliding on ice. The articular cartilage can be seen on x-ray as the space in between the bones.

Incidence of Joint Degeneration

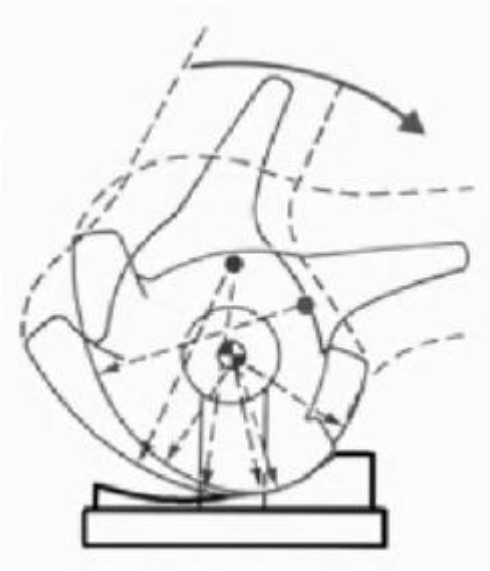


Development and acceptance of knee joint prostheses –slower than that of hip joint

Reason:

- Knee ‘s complicated geometry and biomechanics of movement-it rolls and glides simultaneously
- Lesser stability

a)Freeman-Swanson



b)Spherocentric

c) Walldius

e) Bechtol

Types of artificial knee joints

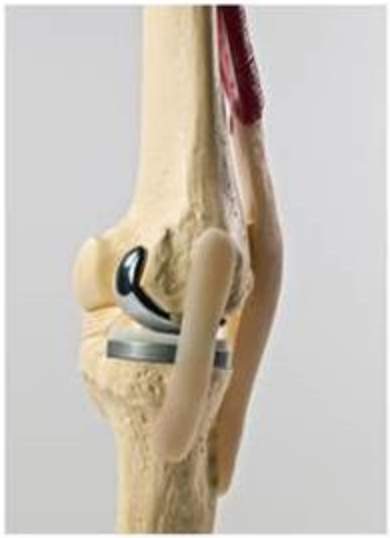
Classification of replacements

- Hinged
- Non-hinged

    -uni-compartmental

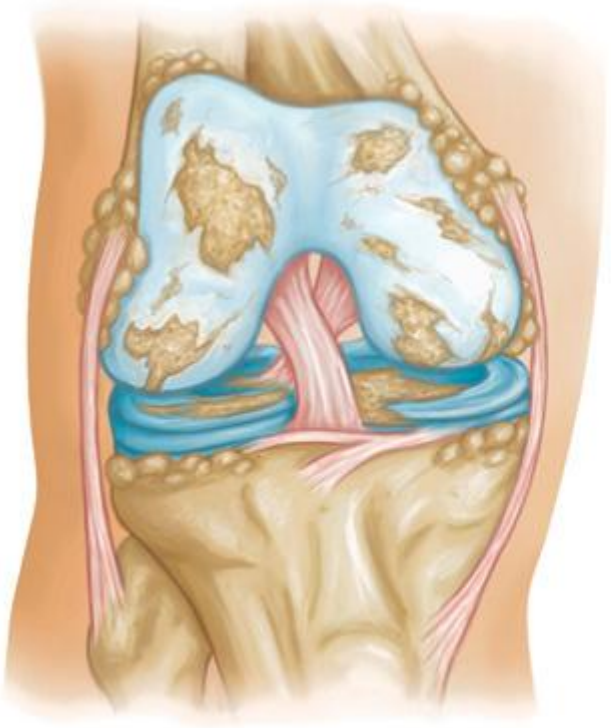
    -bi-compartmental

The knee can be thought of as having 3 compartments - the medial, the lateral, and the patellofemoral. In addition, there are 2 special cartilages within the knee joint called the lateral and medial meniscus, which act as shock absorbers within the knee joint. There are also 2 ligaments within the knee, called the anterior cruciate ligament and the posterior cruciate ligament, which contribute to knee stability.

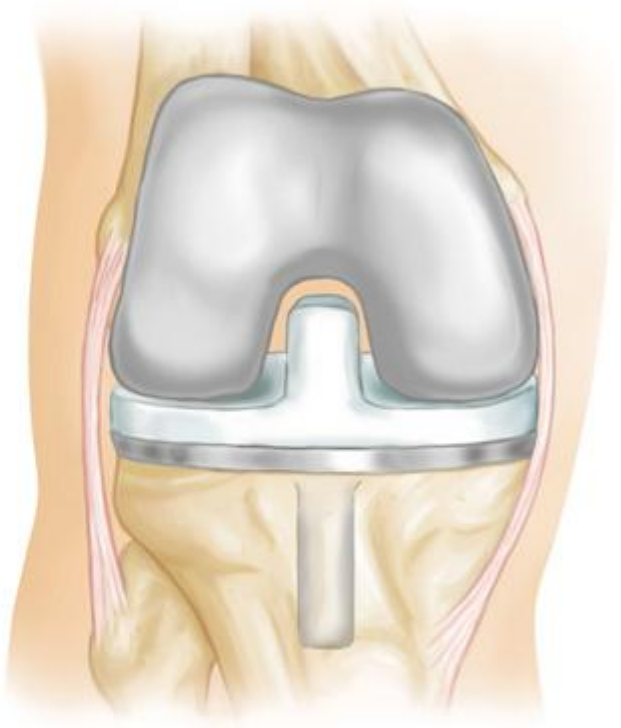


Partial Knee Replacement Implant

Total Knee Replacement Implant



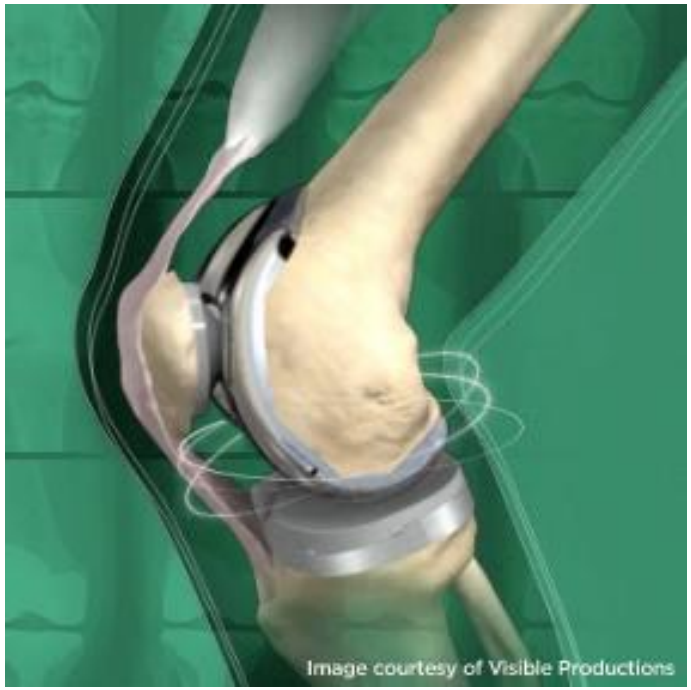
Damaged knee



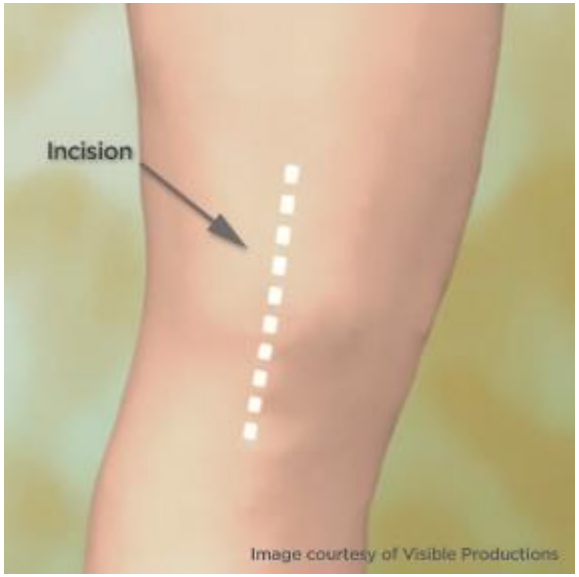
After replacement

Steps of Knee Replacement

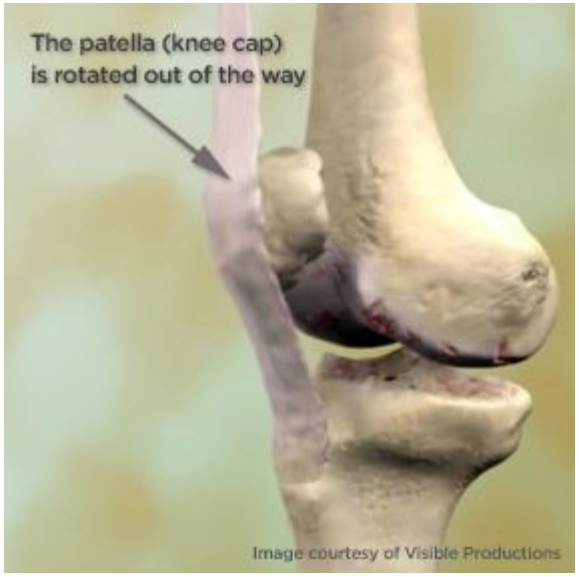
- A total knee replacement (TKR) is a complex procedure that requires an orthopedic surgeon to make precise measurements and skillfully remove the diseased portions of your bone, in order to shape the remaining bone to accommodate the knee implant. During the procedure, the surgeon builds the artificial knee inside your leg, one component at a time, to create a highly realistic artificial joint.



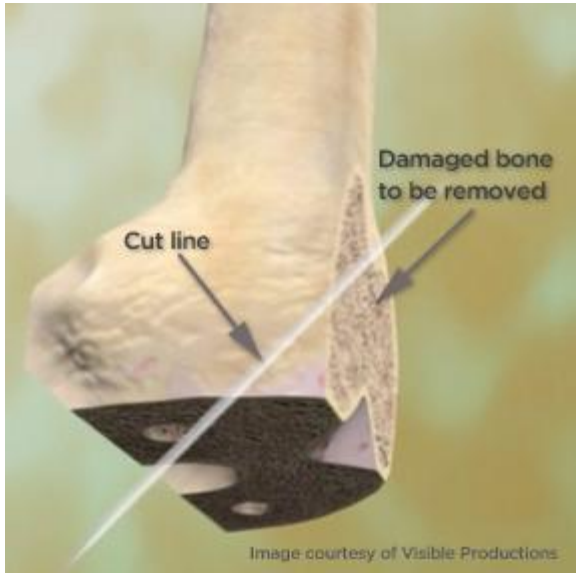
The surgeon makes an incision across the front of your knee to gain access to the patella, more commonly referred to as the kneecap. In a traditional knee replacement, the incision is usually about 8 to 10 inches long. In minimally invasive knee surgery, the incision is usually about 4 to 6 inches long.



The first part of your knee that is exposed is your kneecap, called the*patella*. Once your knee is open, the surgeon rotates the patella outside the knee area. This allows the surgeon to view the area needed to perform the surgical procedure.



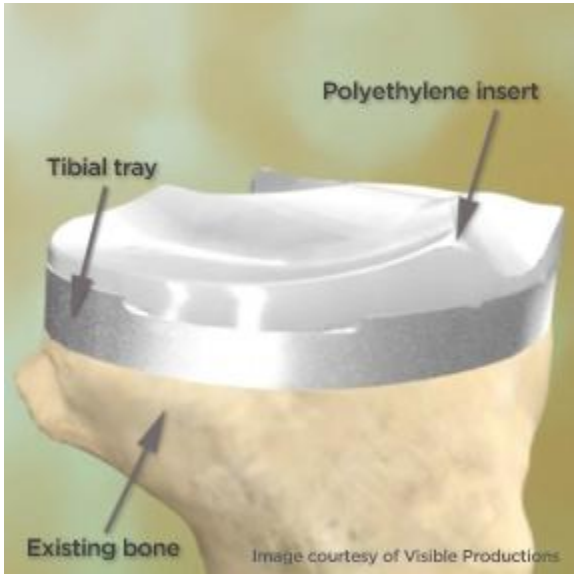
The first bone your surgeon will resurface is your femur, commonly known as the thighbone. Once the surgeon has opened up and exposed your knee joint, he or she will carefully measure your bones and make precise cuts using special instruments. The damaged bone and cartilage from the end of the femur is cut away. The end of your femur is cut and resurfaced to fit the first part of the artificial knee, the femoral component.



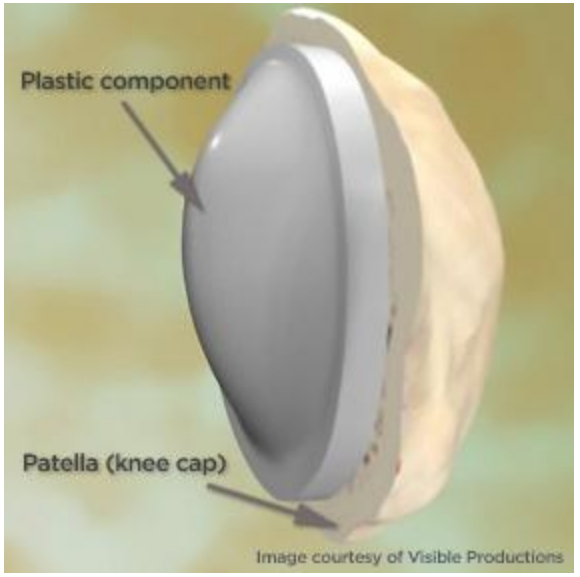
The surgeon attaches the metal femoral component to the end of your femur and uses bone cement to seal it into place.

The next bone your surgeon resurfaces is your tibia, or shinbone. The surgeon removes damaged bone and cartilage from the top of the tibia and then shapes the bone to fit the metal and plastic tibial components.

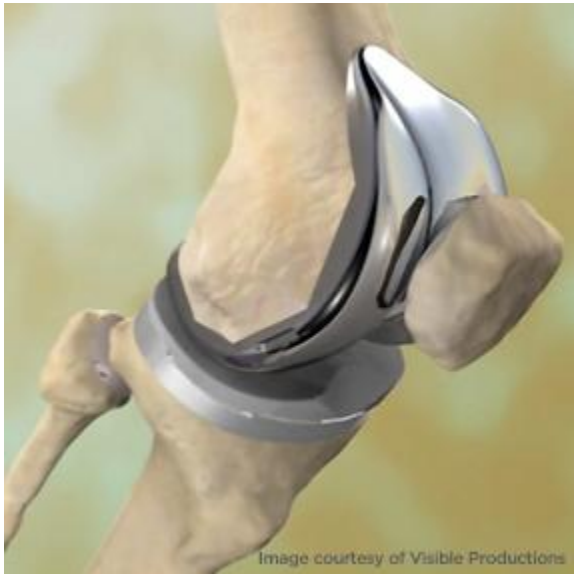
The bottom portion of the implant, called the tibial tray, is fitted to the tibia and secured into place using bone cement. Once the tray is in place, the surgeon will snap in a polyethylene (medical-grade plastic) insert to sit between the tibial tray and the femoral component, and act as a kind of buffer. This insert will provide support for your body as you bend and flex your knee.



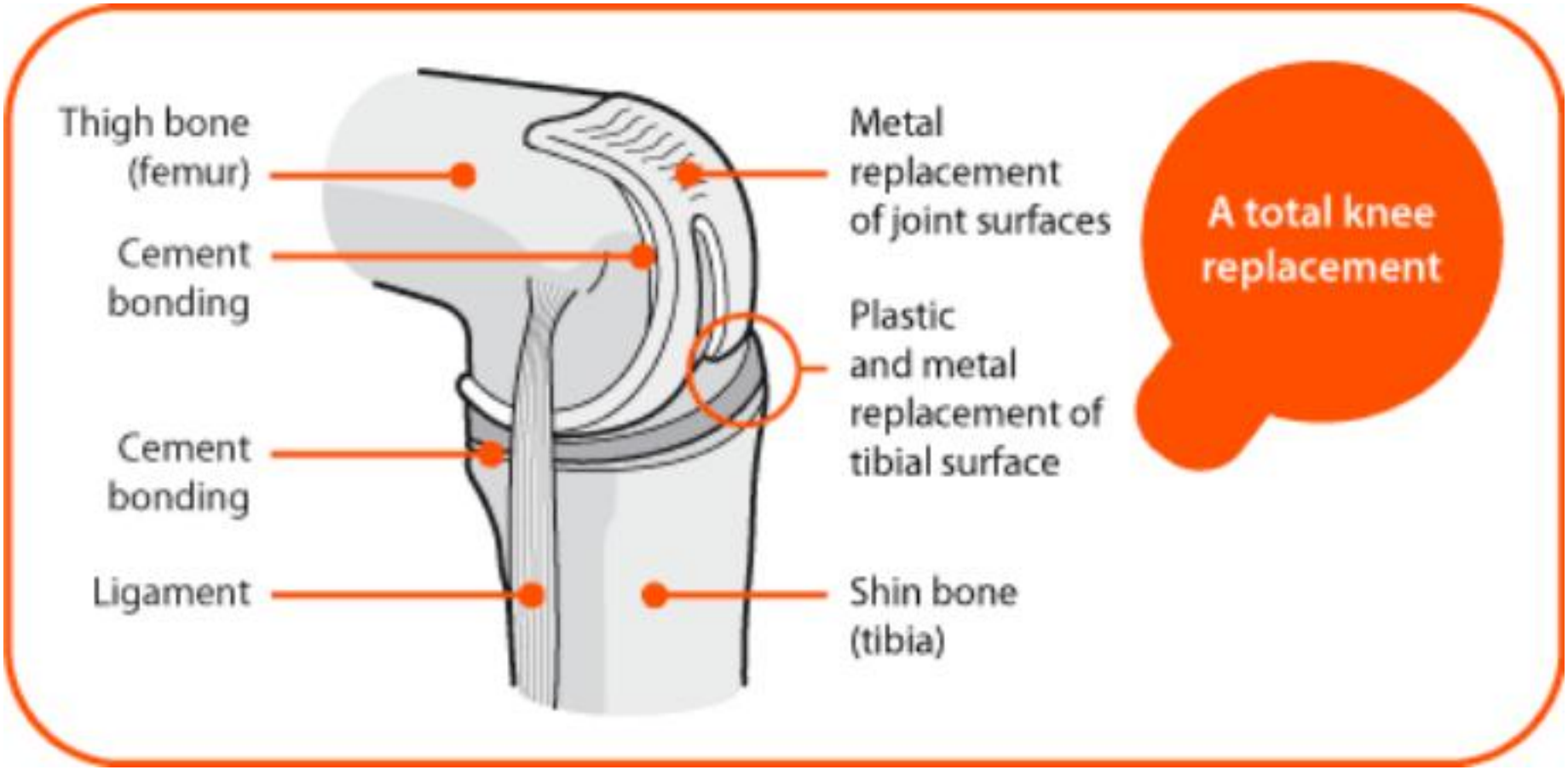
Before returning the patella to its normal position, the surgeon might need to flatten the patella and fit it with an additional plastic component in order to ensure a proper fit with the rest of your implant. The plastic piece, if needed, is cemented to underlying bone.

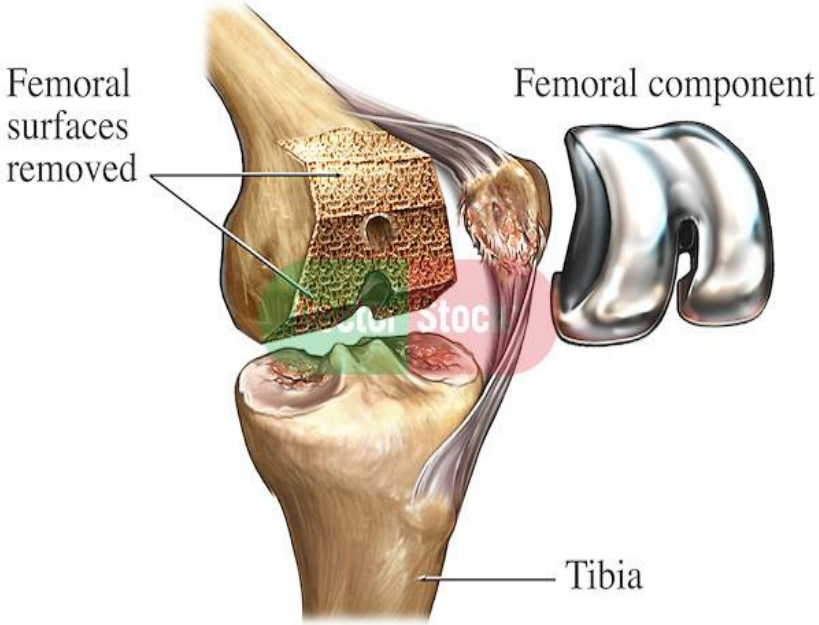


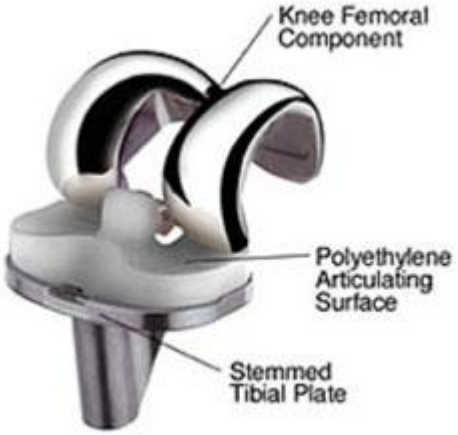
Your surgeon will bend and flex the knee to ensure that the implant is working correctly, and that alignment, sizing, and positioning is suitable. To complete the procedure, the surgeon will close the incision with stitches or staples, and then bandage it and prep you for recovery. You may leave the operating room with your leg in a continuous passive motion (CPM) machine that will gently bend and flex your new knee for you while you are lying down.

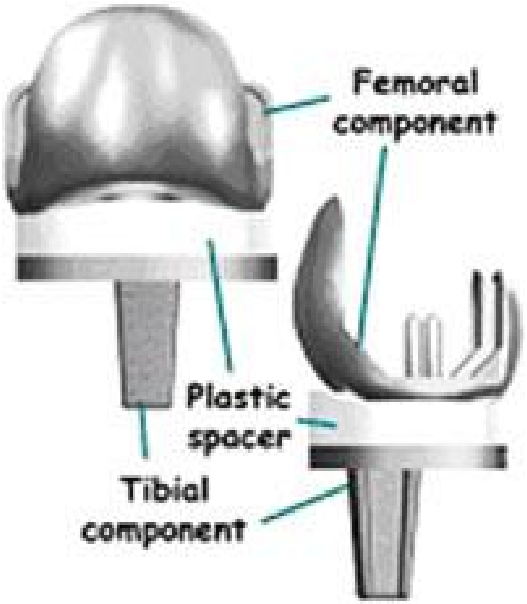


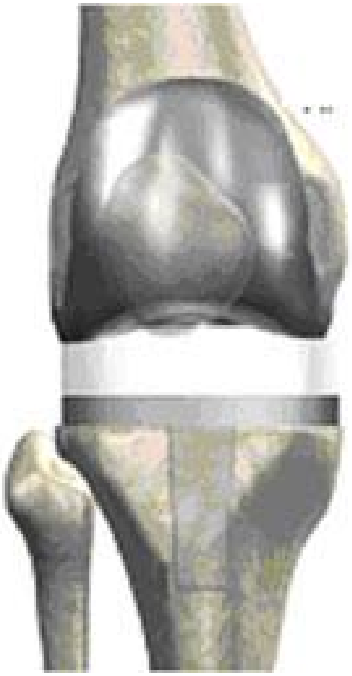
Total knee replacement

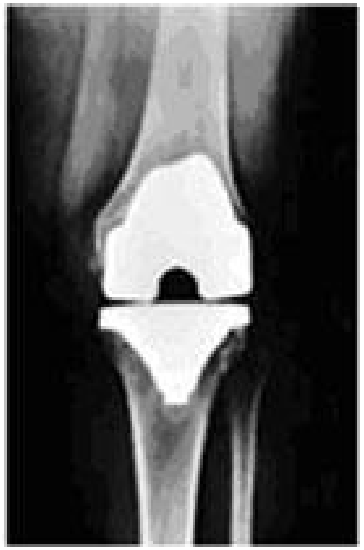



Femoral surfaces removed
Femoral component
Tibia

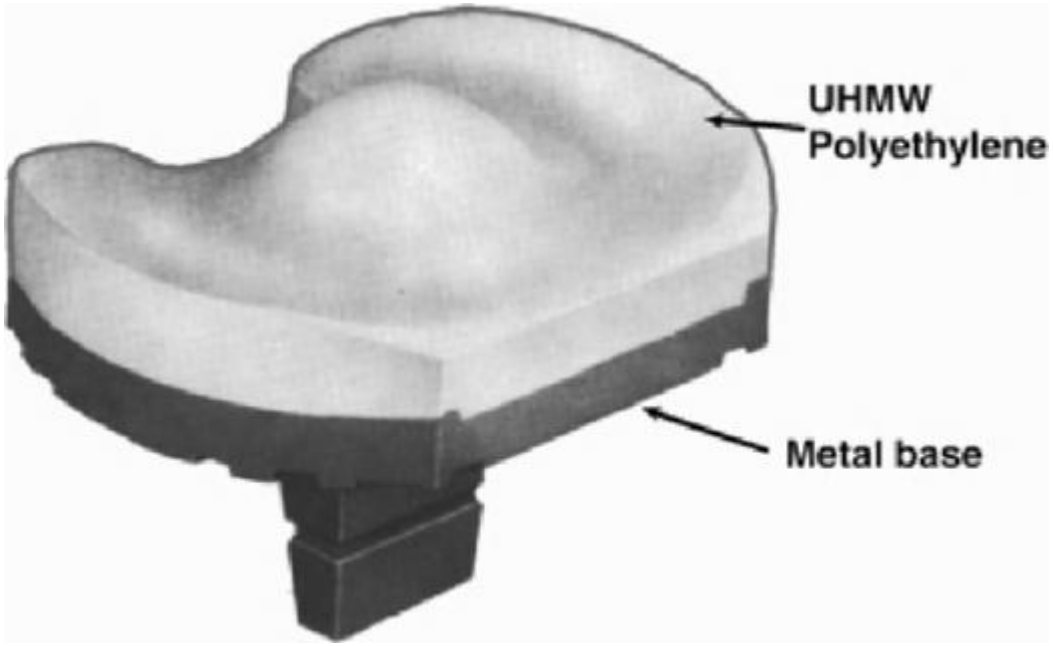

Knee Femoral Component
Polyethylene Articulating Surface
Stemmed Tibial Plate


Femoral component
Plastic spacer
Tibial component

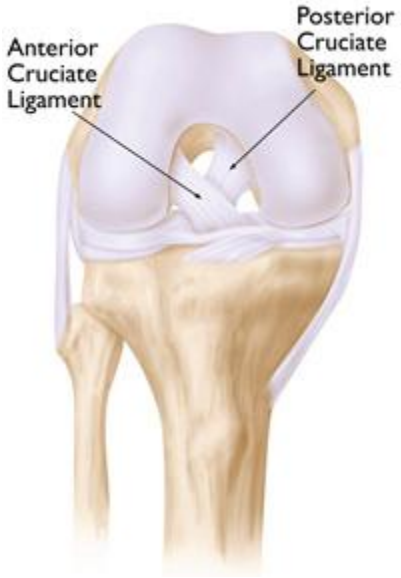




- Total knee replacement surgery was first performed in 1968, and has evolved over the years into a reliable and effective way to relieve disabling pain and allow patients to resume their active lives.



Posterior-Stabilized Designs

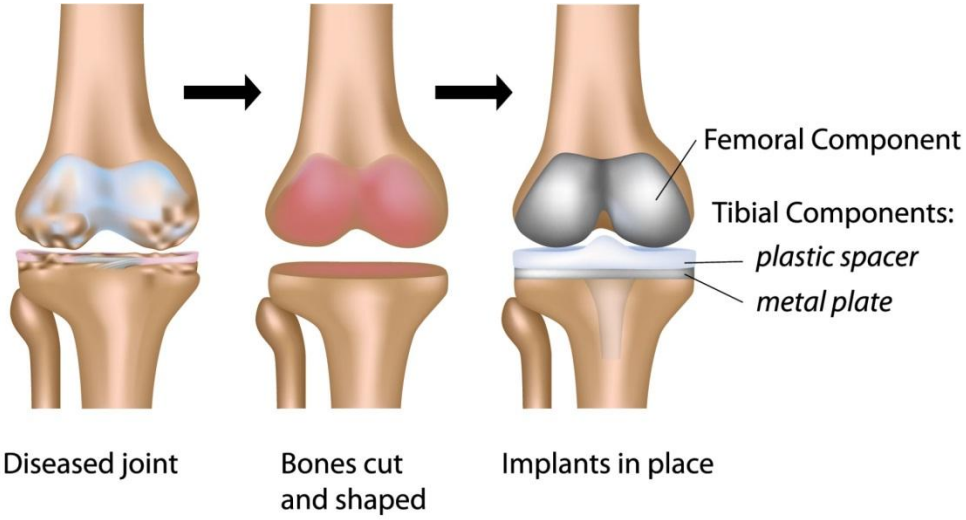


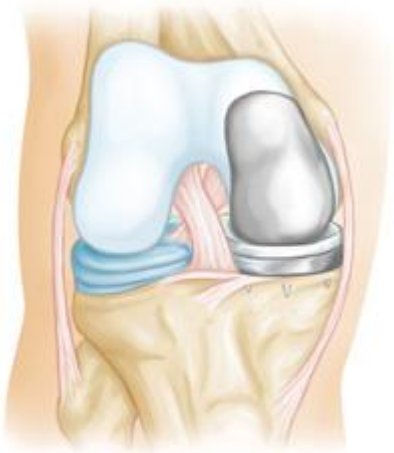
Special bar on femoral component

Tibial Component

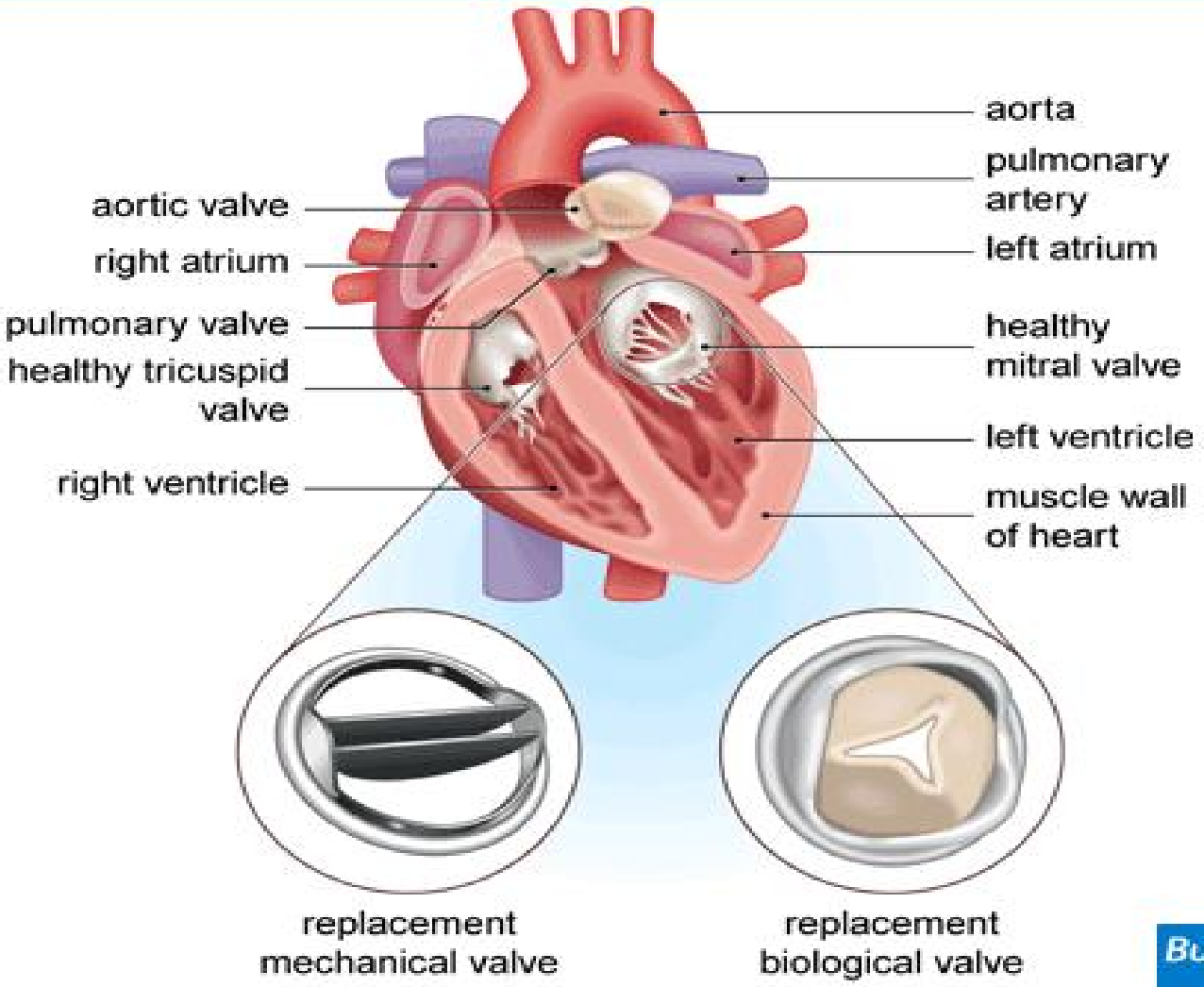
The tibial component has a raised surface with an internal post that fits into a special bar (called a cam) in the femoral component. These components work together to do what the PCL does: prevent the thighbone from sliding forward too far on the shinbone when you bend your knee.

- **Cruciate retaining design**
- **Bicruciate design**
- **Partial or unicompartmental**
- **Total or bicompartmental**

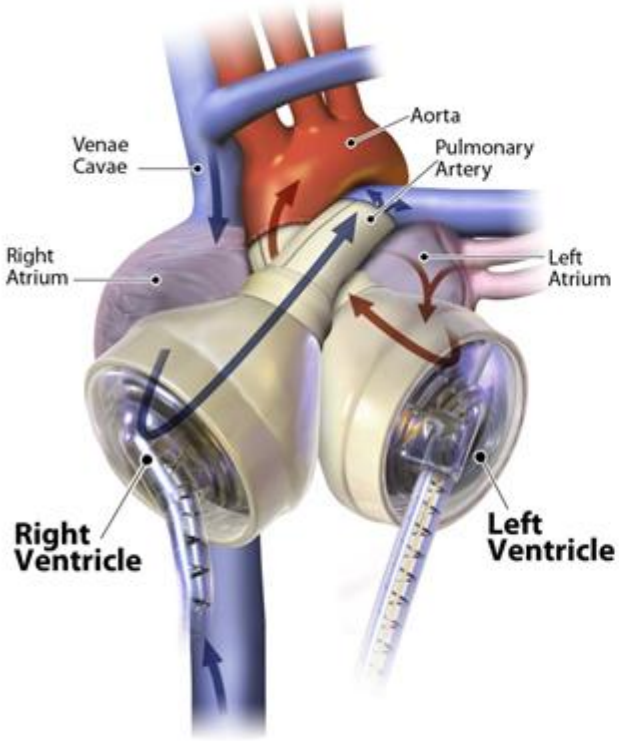




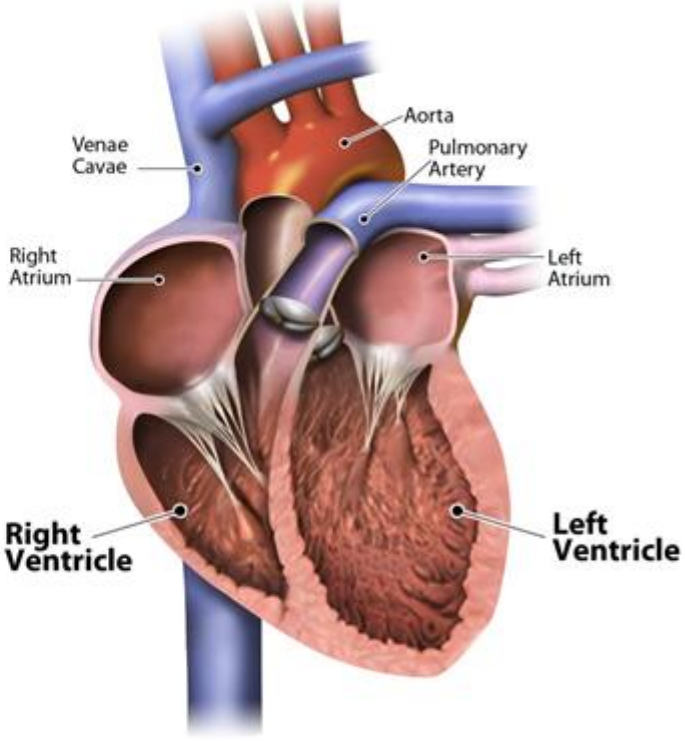
Polymers in heart implant



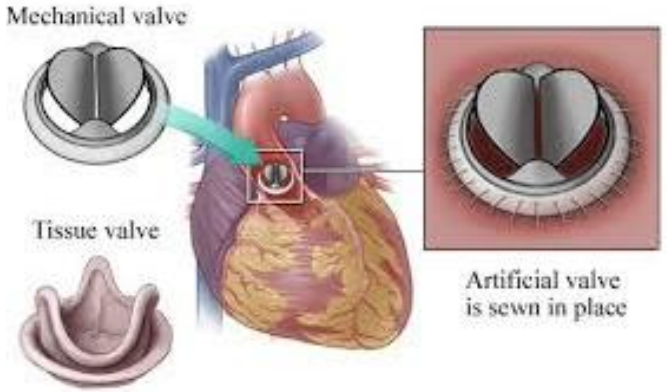
The types of heart valve replacement



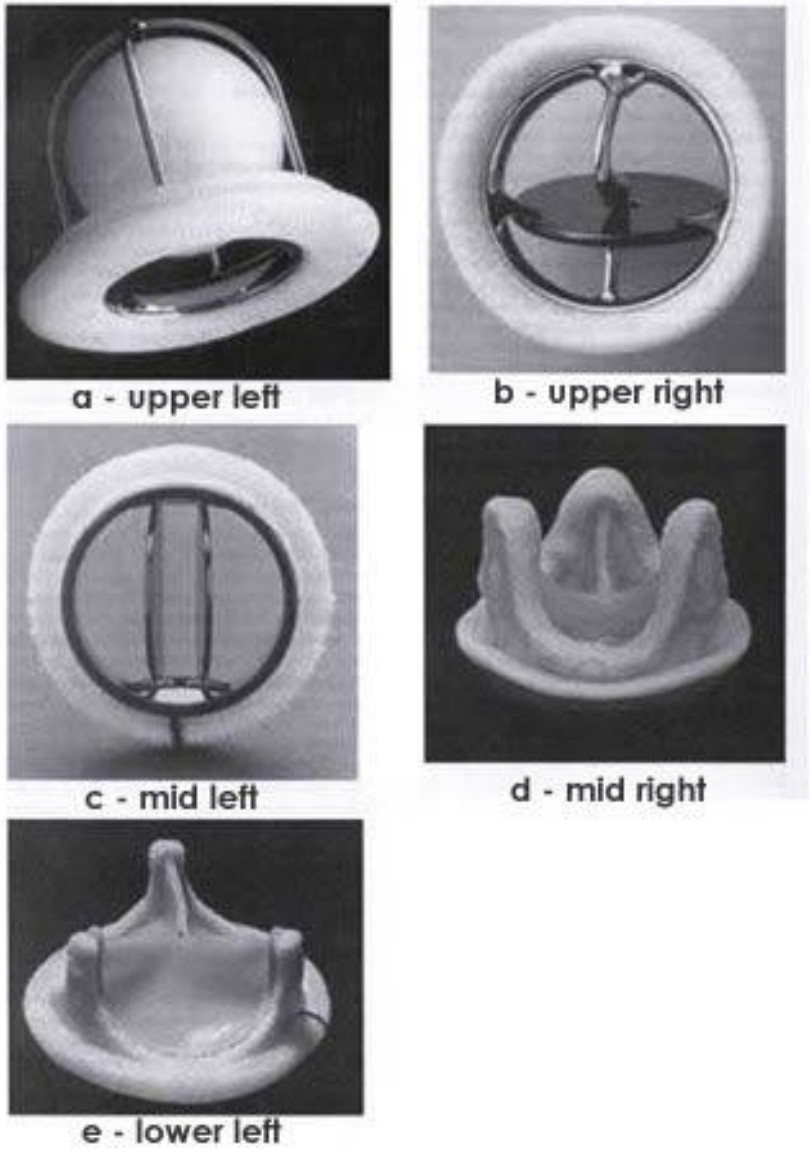
Total Artificial Heart



Human Heart



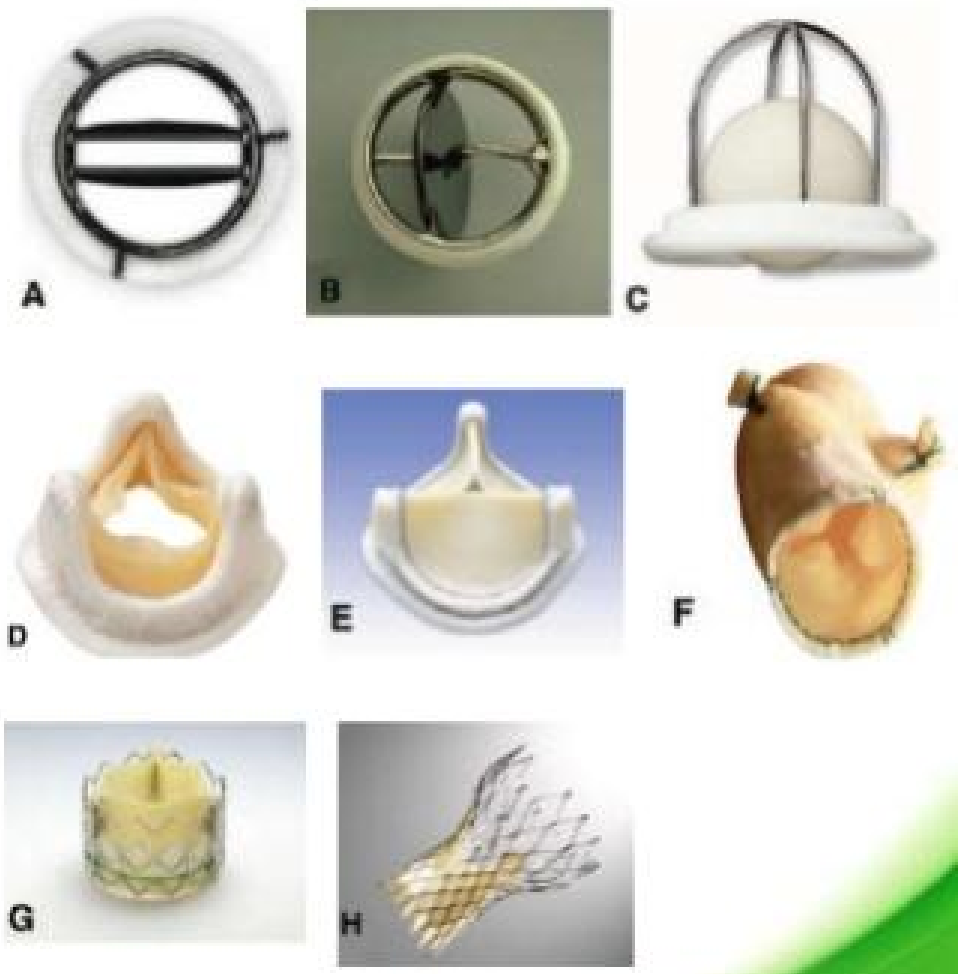
Artificial Heart Valves



Five types of prosthetic heart valves:
A. Starr-Edwards mitral caged ball valve. (Courtesy of Baxter Edwards CVS.)
B. Medtronic Hall tilting disk valve. (Courtesy of Medtronic Heart Valve Division.)
C. St. Jude bileaflet valve. (Courtesy of St. Jude Medical, Inc.)
D. Hancock porcine valve. (Courtesy of Medtronic Heart Valve Division.)
E. Carpentier-Edwards bovine pericardial valve. (Courtesy of Baxter Edwards CVS.)

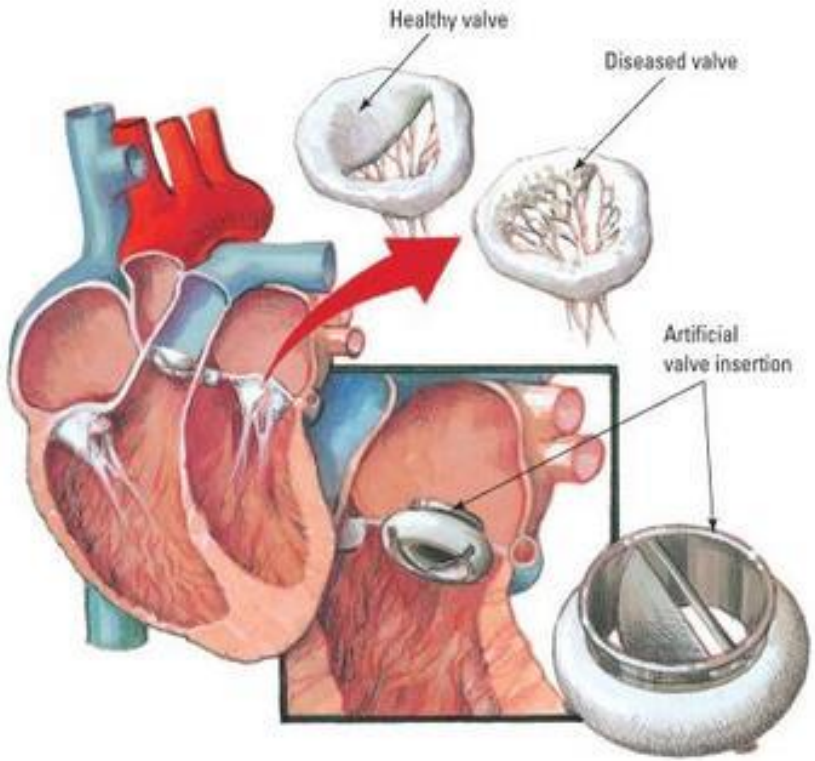
TYPES OF PROSTHETIC HEART VALVES

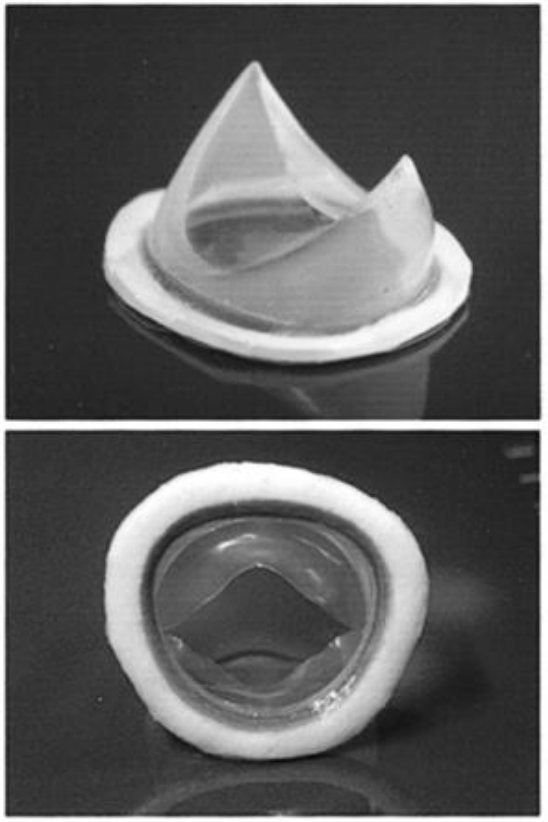
- **Mechanical**
  - **Bileaflet (St Jude)(A)**
  - **Single tilting disc (Medtronic Hall)(B)**
  - **Caged-ball (Starr-Edwards) (C)**
- **Biologic**
  - **Stented**
    - **Porcine xenograft (Medtronic Mosaic) (D)**
    - **Pericardial xenograft (Carpentier-Edwards Magna) (E)**
  - **Stentless**
    - **Porcine xenograft (Medronic Freestyle) (F)**
    - **Pericardial xenograft**
    - **Homograft (allograft)**
  - **Percutaneous**
    - **Expanded over a balloon (Edwards Sapien) (G)**
    - **Self –expandable (CoreValve) (H)**



Circulation 2009, 119:1034-1048

PU based Mitral valve

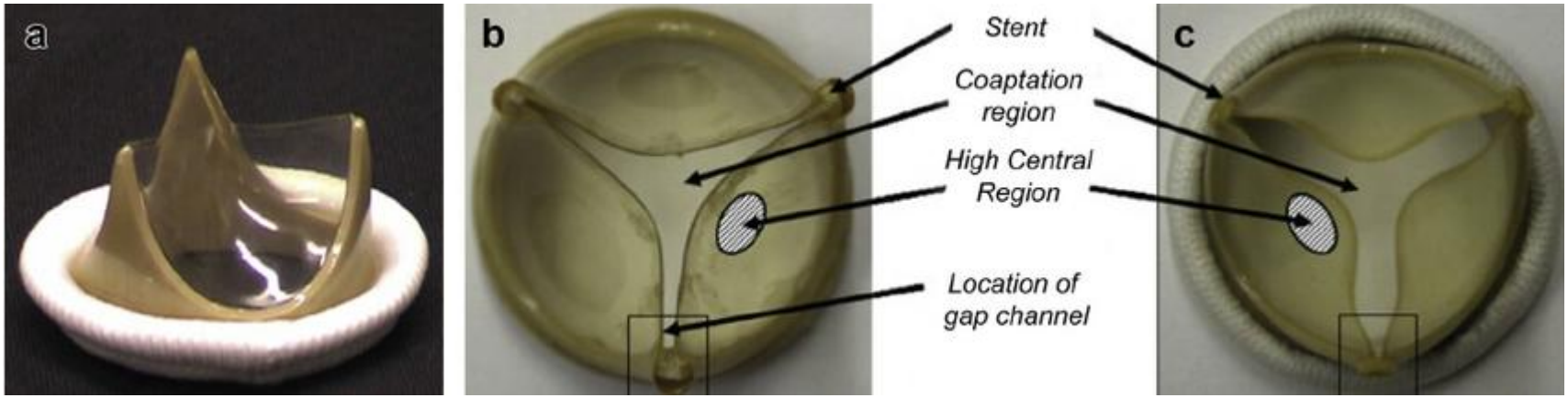




Summary of Various Heart Valve Implantations up to 1994

Types	Model	Year introduced	Total implanted up to 1994
Mechanical			
Ball-in-cage	Starr-Edwards	1965	200,000
Tilting disc			
	Bjork-Shiley		360,000
	Medtronic Hall	1977	178,000
	Omniscience	1978	48,000
	Monostrut	1982	94,000
Bileaflet	St. Jude	1977	580,000
	Carbomedic	1986	110,000
Tissue			
Porcine	Hancock	1970	177,000
	Hancock Modified Orifice	1978	32,000
	Carpentier Edwards (CE)	1971	400,000
	CE Supra Annular	1982	45,000
Porcine (stentless)	Toronto Stentless	1991	5,000
	Medtronic Freestyle	1992	5,000
Pericardial	Carpentier Edwards	1982	35,000
Homograft	Various	1962	28,000
Autogenous	Pulmonary	1967	2,000

Artificial tricuspid valve



Mile Stones

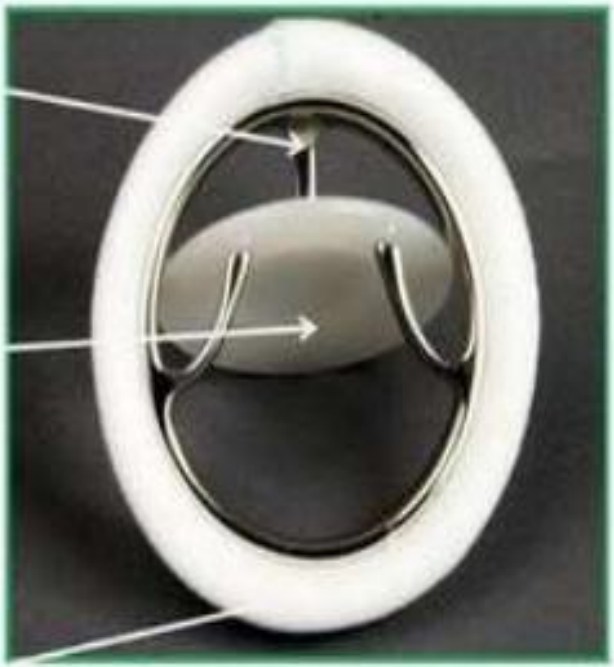
- The first human implant was December 6, 1990 at Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.
- In Clinical use for over 14 years.
- More than 55,000 TTK Chitra Heart Valve has been implanted so far in India, Nepal, Sri Lanka, Bangladesh and South Africa, Thialand
- Crossed over 1,00,000 patient years
- Award for TTK Chitra heart valve prosthesis
  Hinduonnet
- Award for TTK Chitra heart valve prosthesis
  May 17, 2001, Medindia

- **Materials of Construction**
- The three main components of TTK Chitra Heart Valve are:
- Frame
- Disc
- Sewing Ring

FRAME
Haynes-25 Alloy

DISC
Ultra High Molecular Weight Polyethylene

SEWING RING
Warp Knitted Polyethylene Terephthalate (Polyester) fabric



- Tilting Disc
  - pivoted eccentrically in the metallic frame.
  - MADE FROM ULTRA HMW POLY ETHYLENE
- The sewing ring
  - POLYETHYLENE TEREPTHALATE (PET)
  - fitted snugly around the frame
  - used to suture the valve in the intended position in the heart.

  FRAME: COBALT CHROMIUM ALLOY(HAYNES 25)

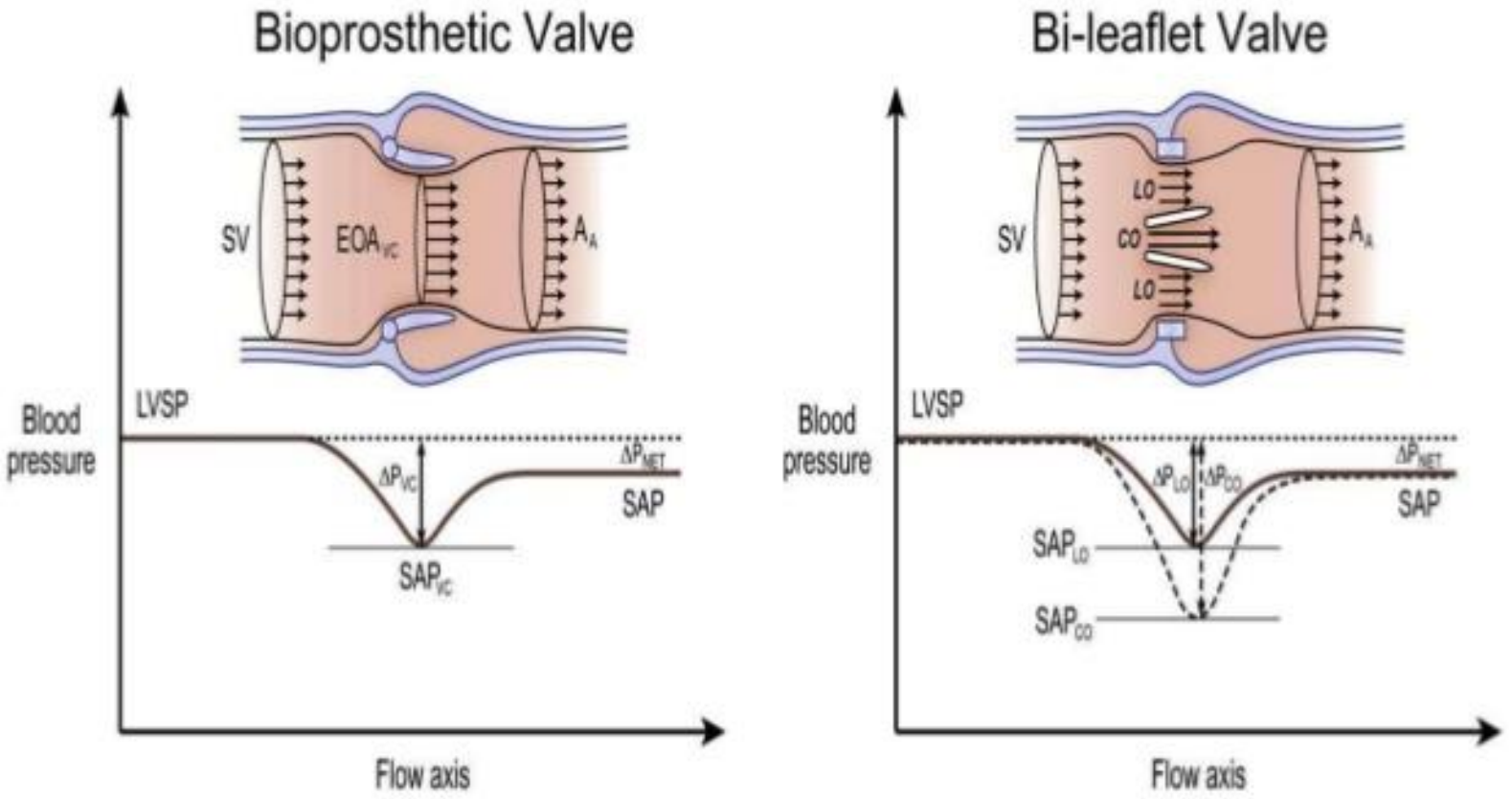
- The frame and the disc are ***hydro dynamically designed to reduce drag and inertia*** and **polished** to minimize the chances of clotting.

Pyrollitic carbon is used to coat the metal frame

Requirements

- The artificial valve **must withstand the stress** of opening and closing some 40 million times a year.
- The materials used for the valve ***have to be compatible with blood*** and human tissues.
- When open, the valve **should allow the blood to flow smoothly** through.
- Once closed, the **back flow of blood had to be minimal.**

Pressure Recovery



- The smaller central orifice in bileaflet valves may give rise to a high-velocity jet
- that corresponds to a localized pressure drop
- that is largely recovered once the central flow reunites with flows originating from two lateral orifices

Biocompatibility Evaluation

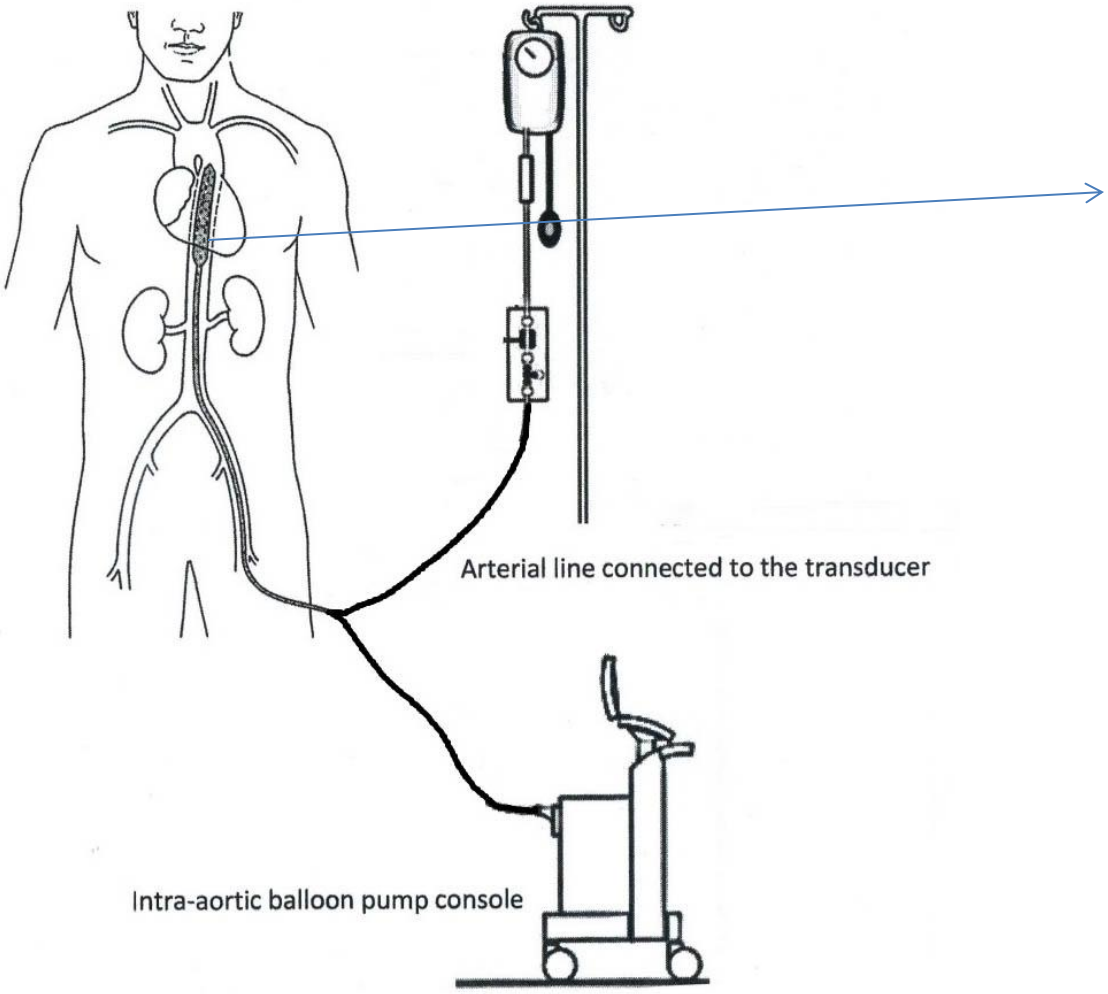
- All the materials used in the valve have undergone ***extensive toxicological and implant evaluation*** that is applicable to permanent implants.

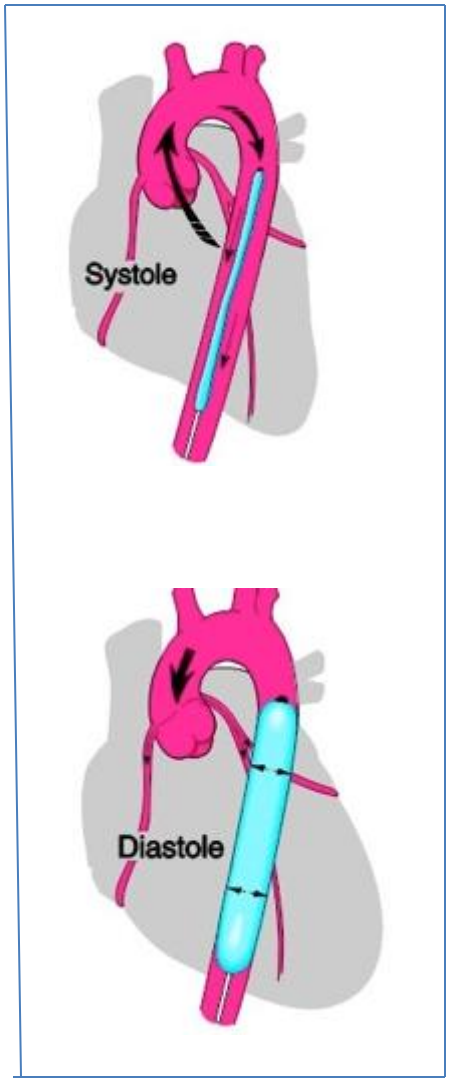
- As per the ISO protocol for artificial heart valves, the TTK Chitra Heart Valve has passed through ***rigorous in vivo animal trials in sheep.***

- During the trial, the valves were implanted in the mitral position without any anticoagulation regimen for the animals.

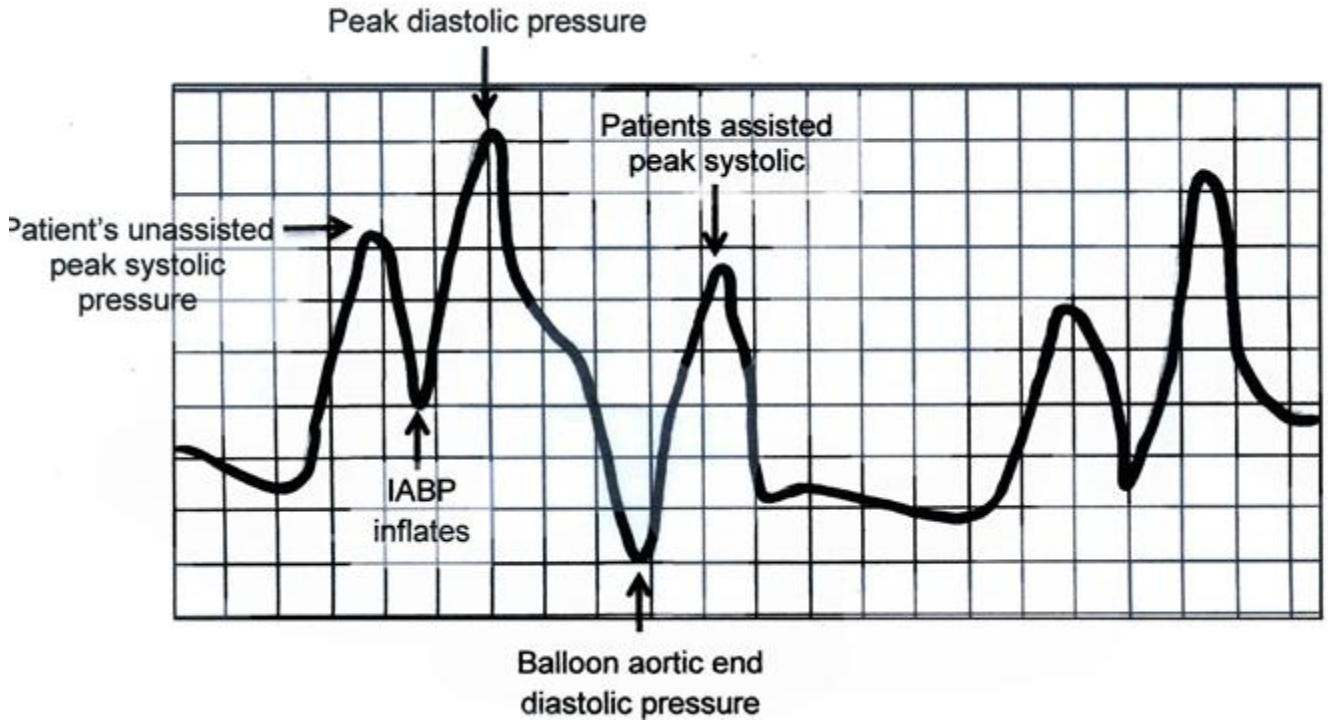
- The long time survival of these animals even under these difficult conditions was uneventful.

Intra Aortic Balloon Pump

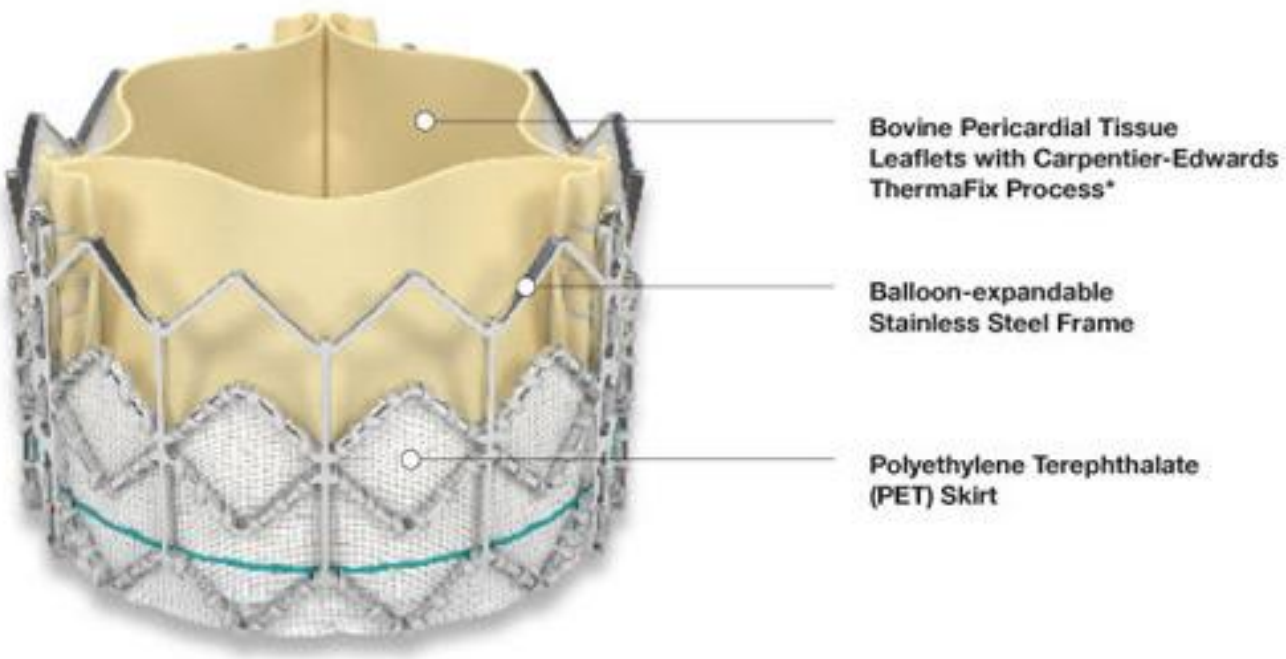




Normal balloon inflation

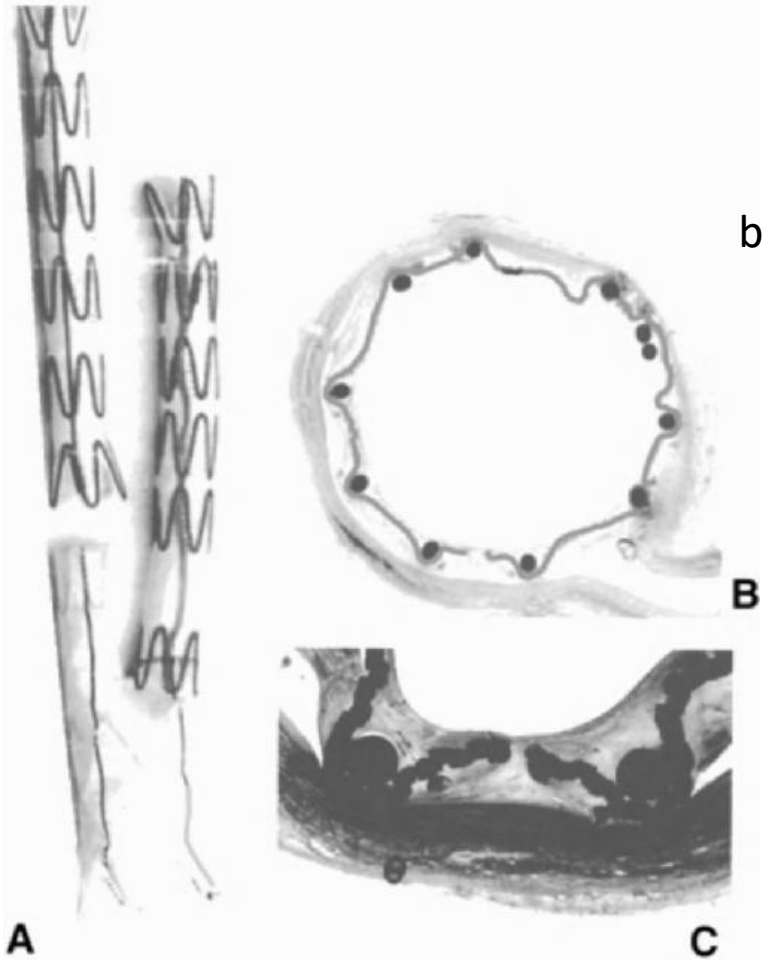


When balloon-assisted, the diastolic pressure should always be the highest pressure recorded on the waveform. This will ensure that the coronary arteries receive the maximum blood flow. The balloon-assisted systolic pressure should be lower than the patients non-assisted, systolic pressure due to the reduction in afterload.


Bovine Pericardial Tissue
Leaflets with Carpentier-Edwards
ThermaFix Process*
Balloon-expandable
Stainless Steel Frame
Polyethylene Terephthalate
(PET) Skirt

Xenograft

Cardiovascular stents

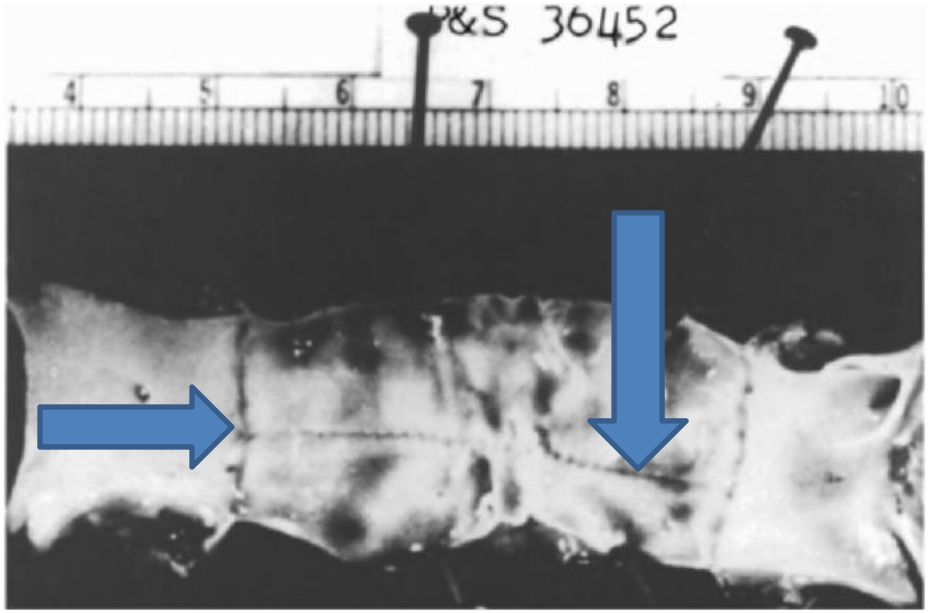


Stent grafts. (**a**) Configuration of device showing composite metal and fabric portions

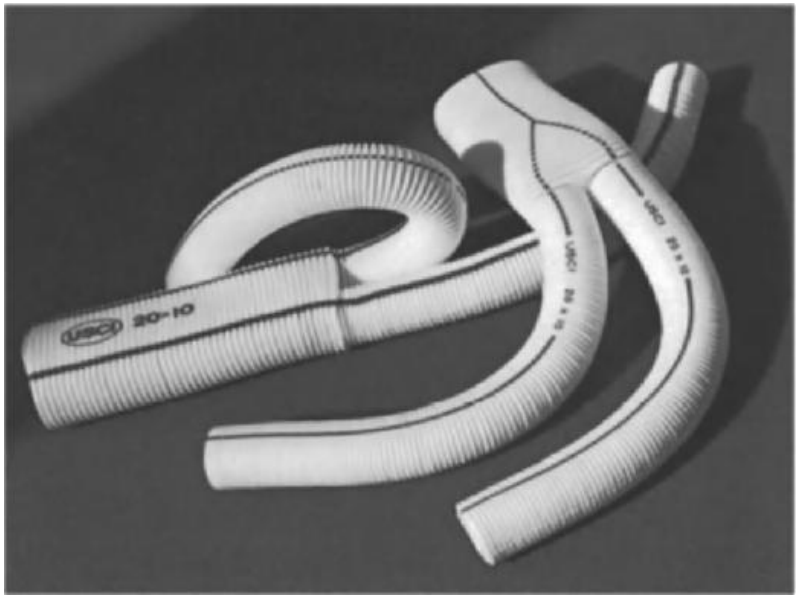
b)well-healed experimental device explanted from a dog aorta. The lumen is widely patent and the fabric and metal components are visible.

c)High-power photomicrograph of stent graft interaction with the vascular wall, demonstrating mild intimal thickening.

Porous vascular implant



First arterial implant stitching fabrics with hand



Modern arterial implant

Types

Classification on the basis of materials used:

- Bare metallic stents
- Coated stents
- Drug eluting stents
- Biodegradable stents

Metallic stents

- Requirements:

Expandable-ability to plastic deformation, sufficient elasticity to be compressed for delivery and then expanding in the target area

Radial hoop strength and negligible recoil-should not collapse after implantation

Low profile-ability to be crimped on the balloon catheter supported by a guide wire

Adequate radio-opacity/MRI compatibility

Thromboresistivity -blood compatible

Drug delivery capacity

Metals- Stainless steel , Ta, Pt-Ir alloy, Ti, Ni-Ti alloy , Co-Cr

Biodegradable metallic stents-Pure Fe, Mg alloys(+Al+Zr+rare earth metals)

Surface Characteristics of stent

- **Surface energy**-surface chemistry-wettability, thrombogenicity- PET,PTFE, PU compared-PU least surface energy,hydrophilic coating on SS stents reduces accumulation of platelets
- **Surface texture**-Polishing is essential –rough surface causes thrombosis
- **Surface potential**-Metals are electropositive and blood elements are electronegative-accentuates thrombogenicity-coating the metal surface by biological / inorganic/ polymeric materials
- **Stability of surface oxide layer**-acts as barrier to the release of ions from the bulk materials underneath the surface.

Rationale for coatings

- Thrombosis and neo-intimal hyperplasia-major problem

Effect of coating:

- Surface energy gets reduced
- Surface texture smoothened
- Surface potential neutralized
- Stability of surface oxide layer enhanced

Types of methods of Coating:

- **Galvanization**
- **Sputtering followed by bombarding ions**
- **Pulsed biased arc ion plating**
- **Dipping**
- **spraying**
- **plasma based depositions**

Materials used in coating

- Inorganic Coating-gold, silicon carbide, Iridium oxide, diamond like Carbon(ceramic)
- Endothelial cells-(Biological)
- Porous materials-PU films with 30µm pores
- Polymers

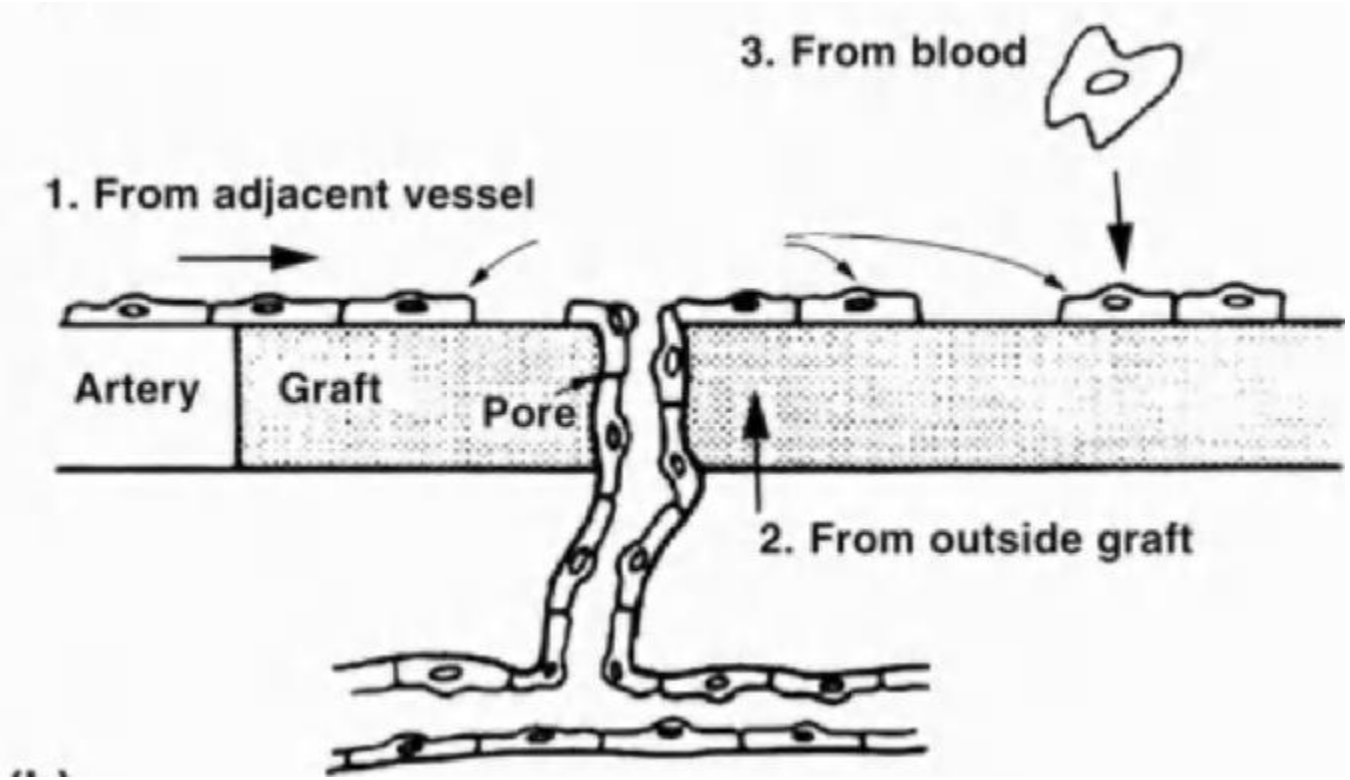
Metallic/Inorganic Coatings(ceramic)

- Gold –preferred on SS to enhance fluoroscopic visibility-reduced neo-intimal hyperplasia on gold coated (thermally processed) SS surface-due to smoothness and removal of embedded impurities in the gold surface for porcine coronary arteries but in human trials it was not satisfactory.
- Iridium oxide- It reduces inflamamtory reactions of metal by the conversion of H_2O_2 to water and oxygen
- Silicon-carbide –amorphous hydrogenated SiC is a semiconductor and antithrmbogenic
- Carbon- chemically inert, biocompatible

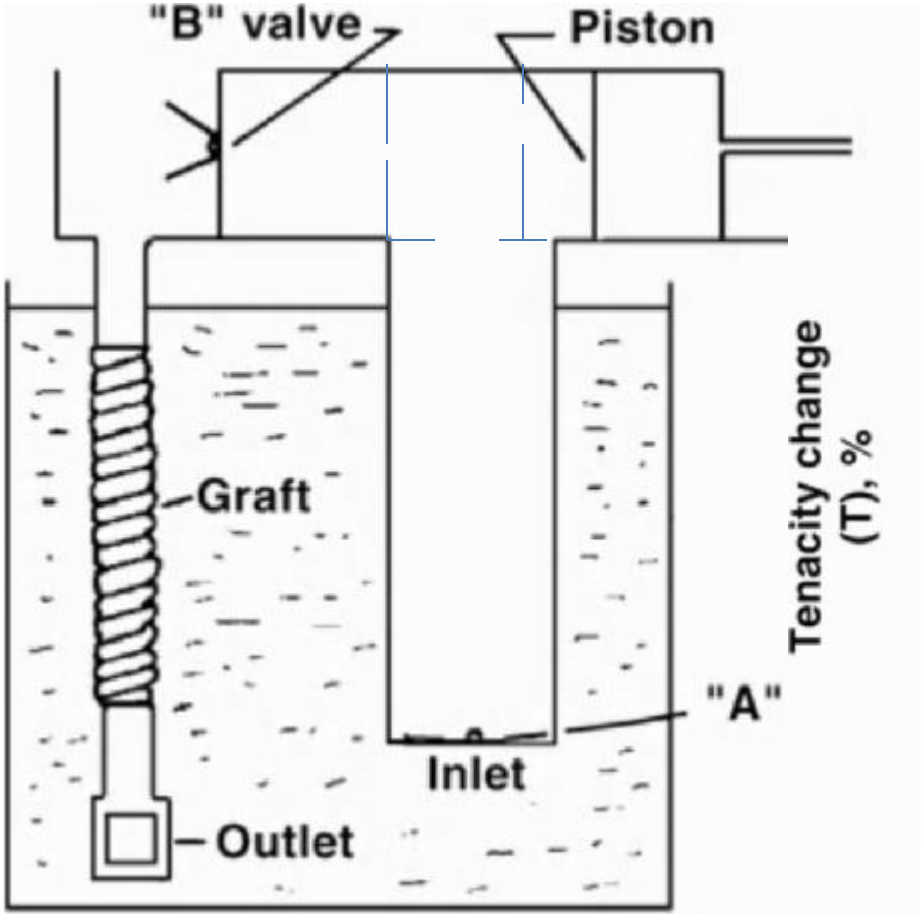
Polymer coating

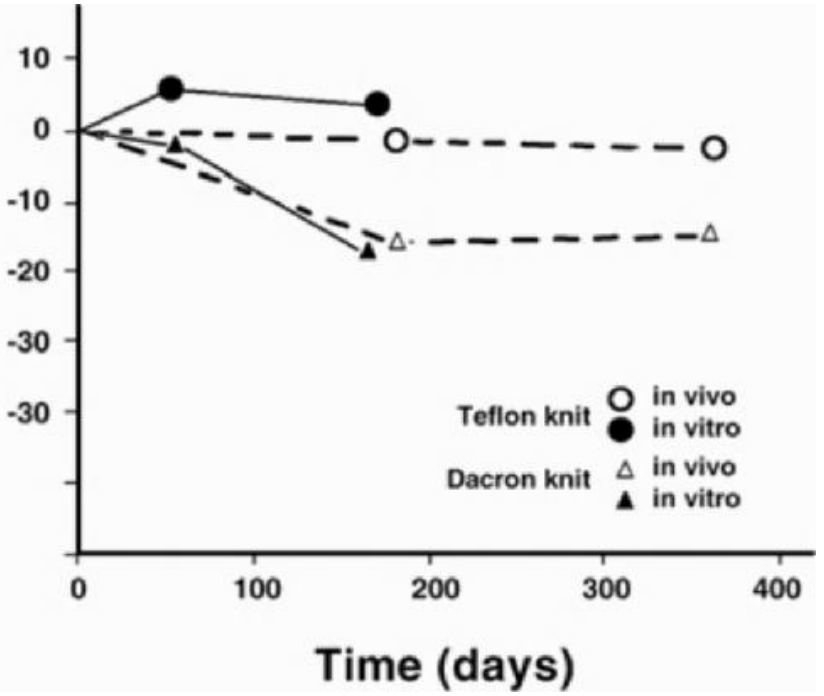
- Bio-stable (not biodegradable) polymers
- Biodegradable
- Copolymers
- Biological polymers

Tissue ingrowth and fixation of stents

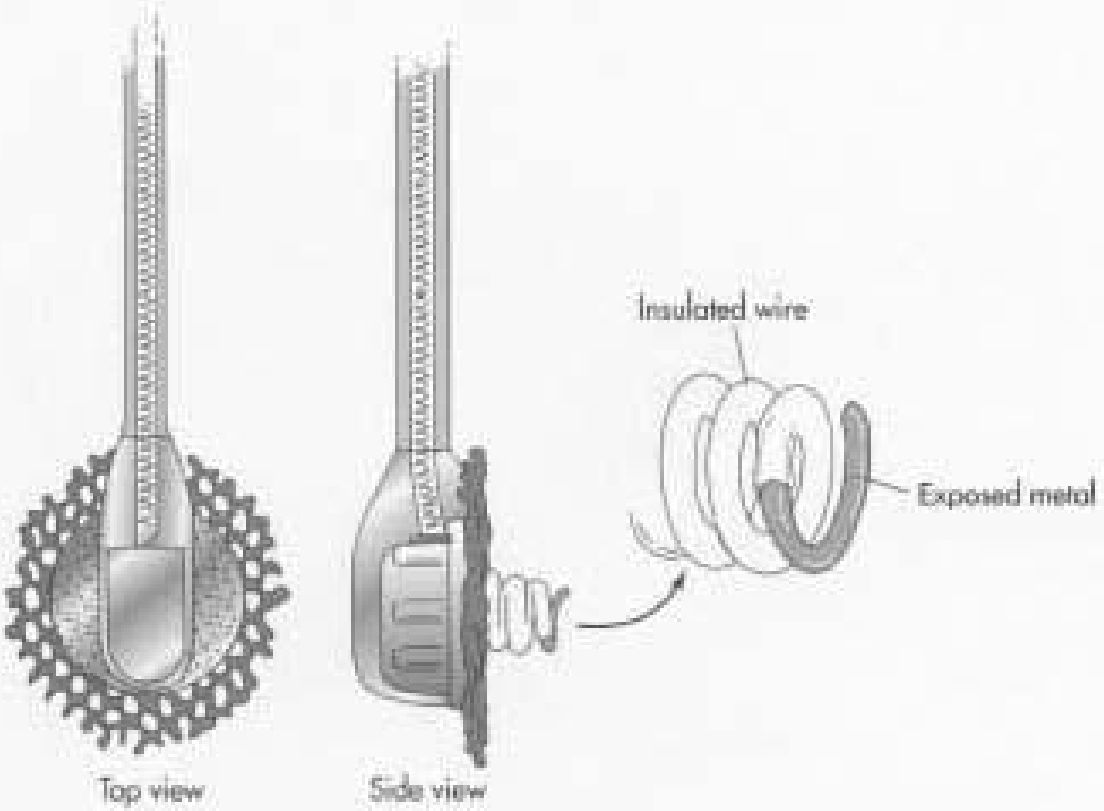


Schematic diagram of arterial graft life tester





Artificial heart implant devices

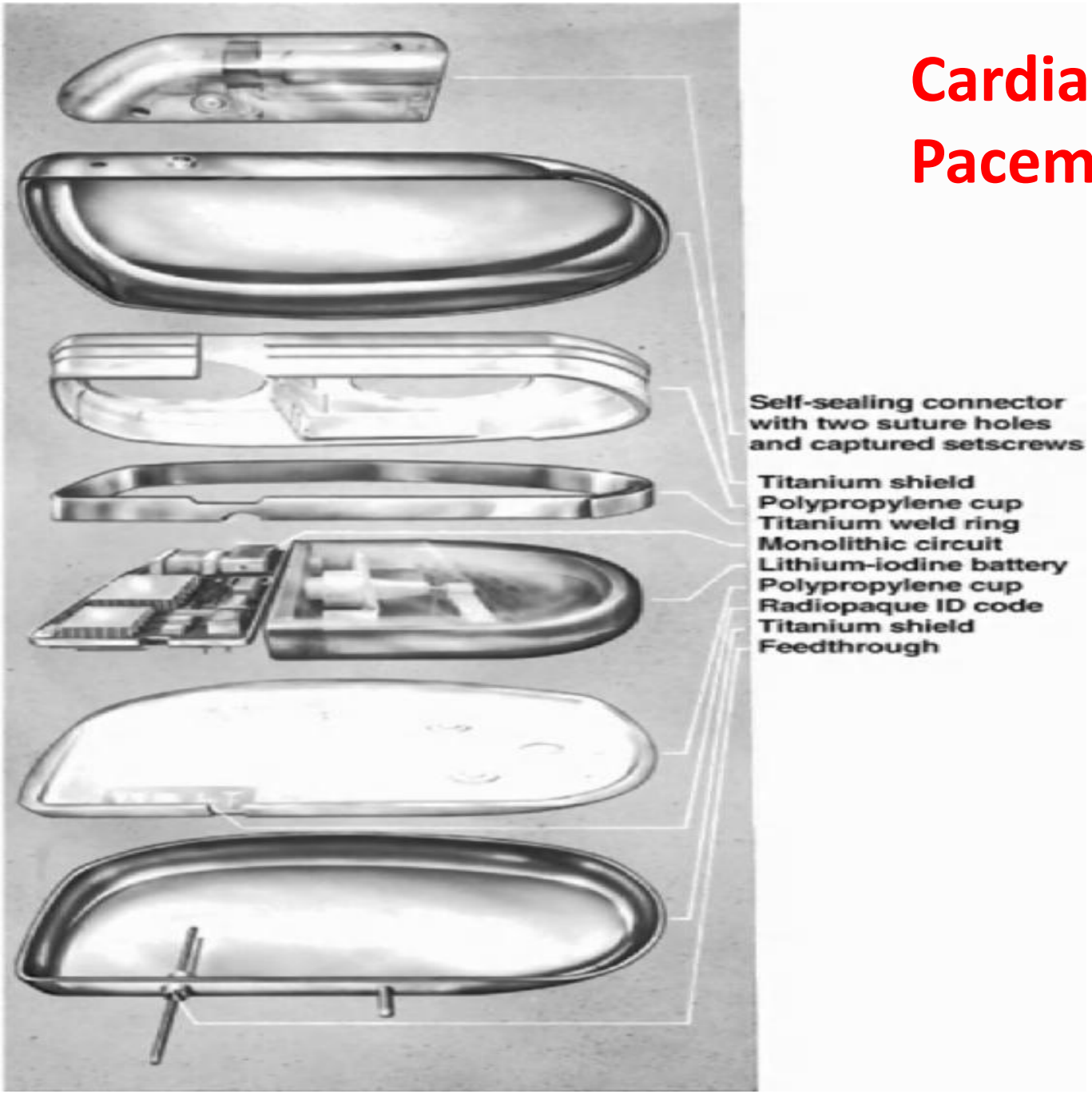


Pacemaker electrode with a screw-in lead that helps anchor it to the wall of the heart. The lead is made of a metal alloy and insulated by polymer such as polyurethane.

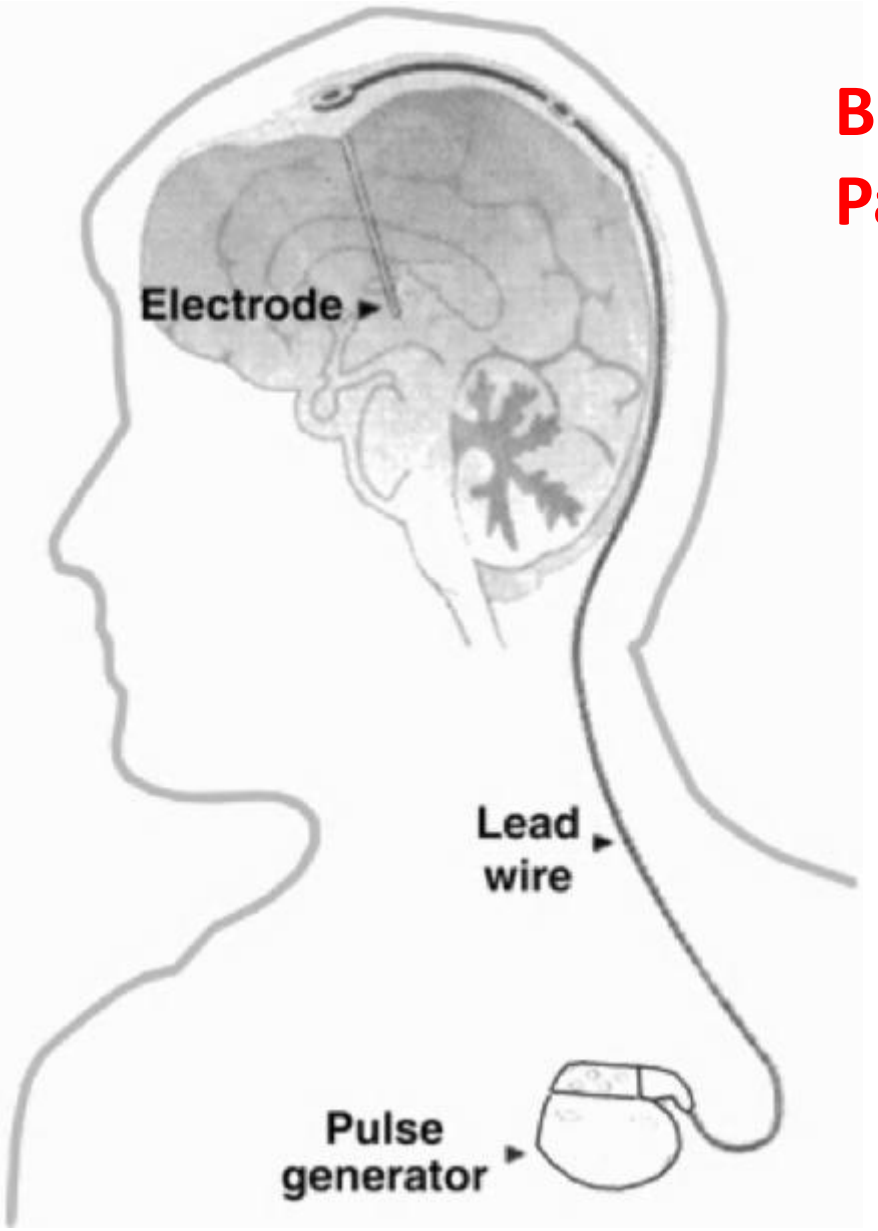
Major applications

- Catheters and tubings
- Artificial heart
- Cardiac assist device-Intra aortic balloon(IAB)

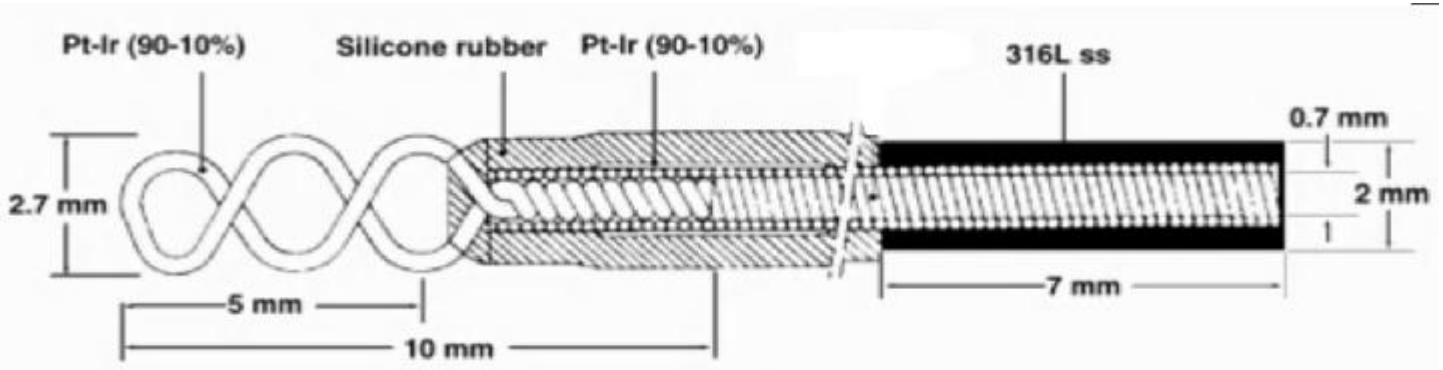
Cardiac Pacemaker

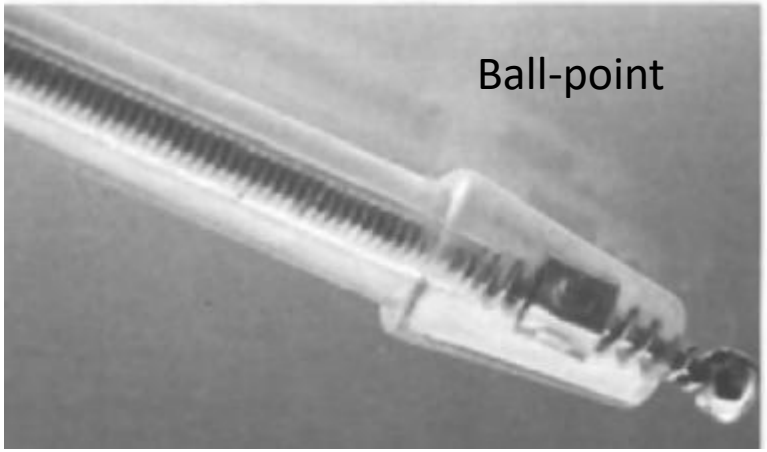


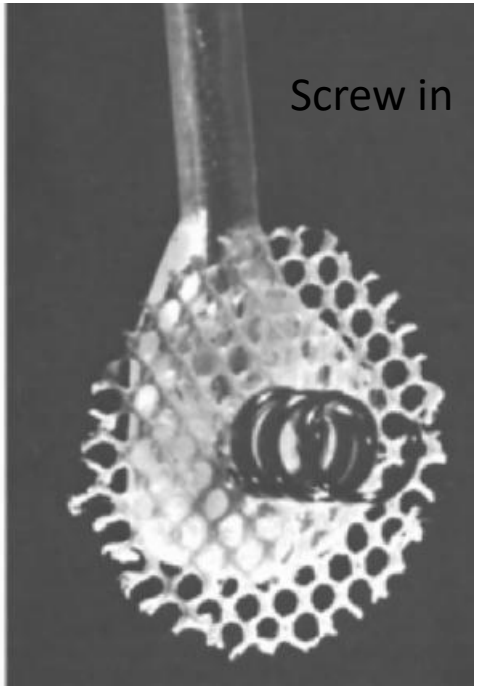
Brain Pacemaker

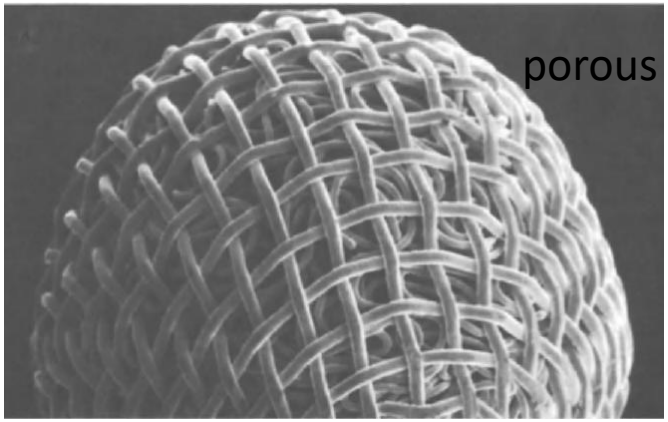


Details of an arterial electrode

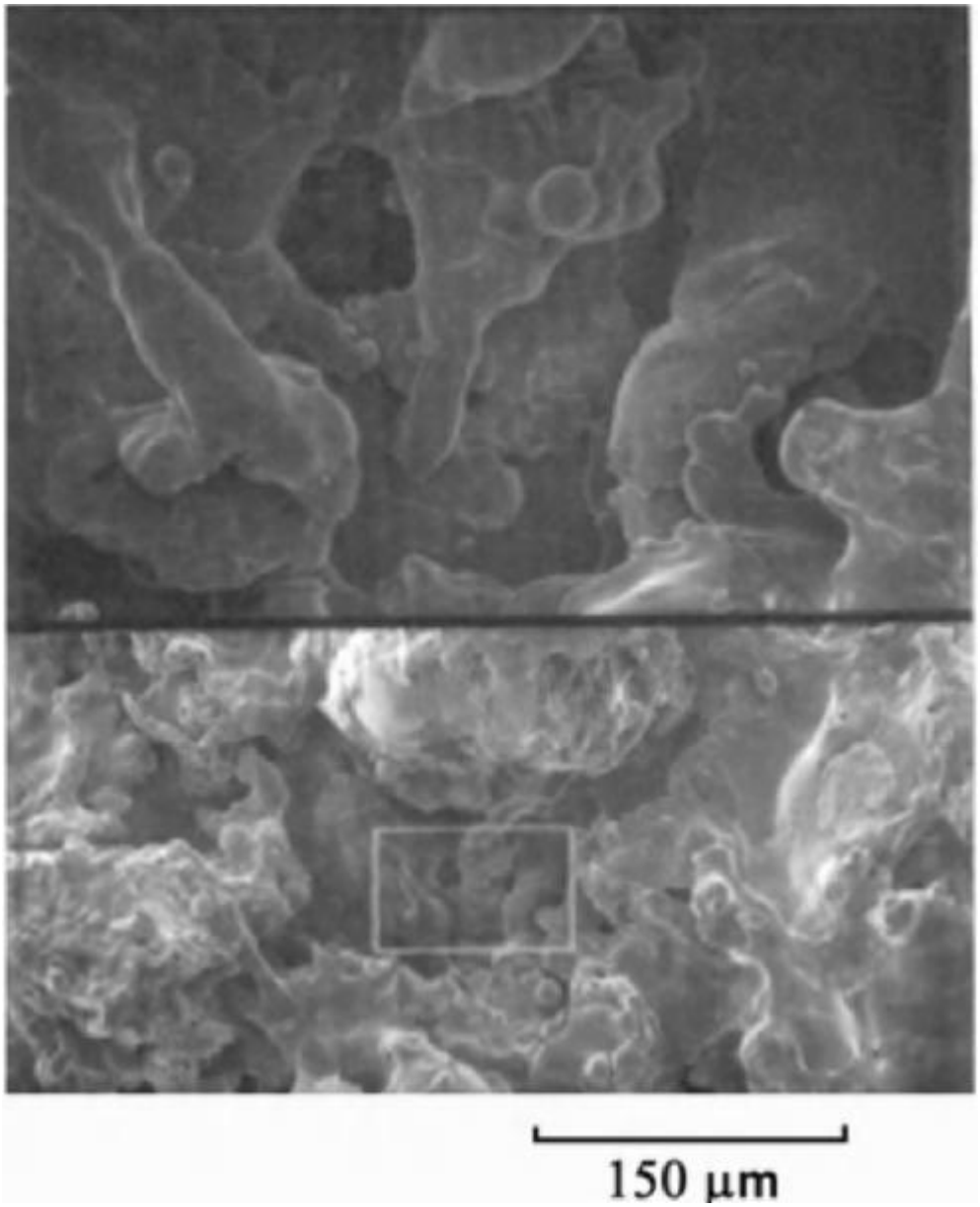






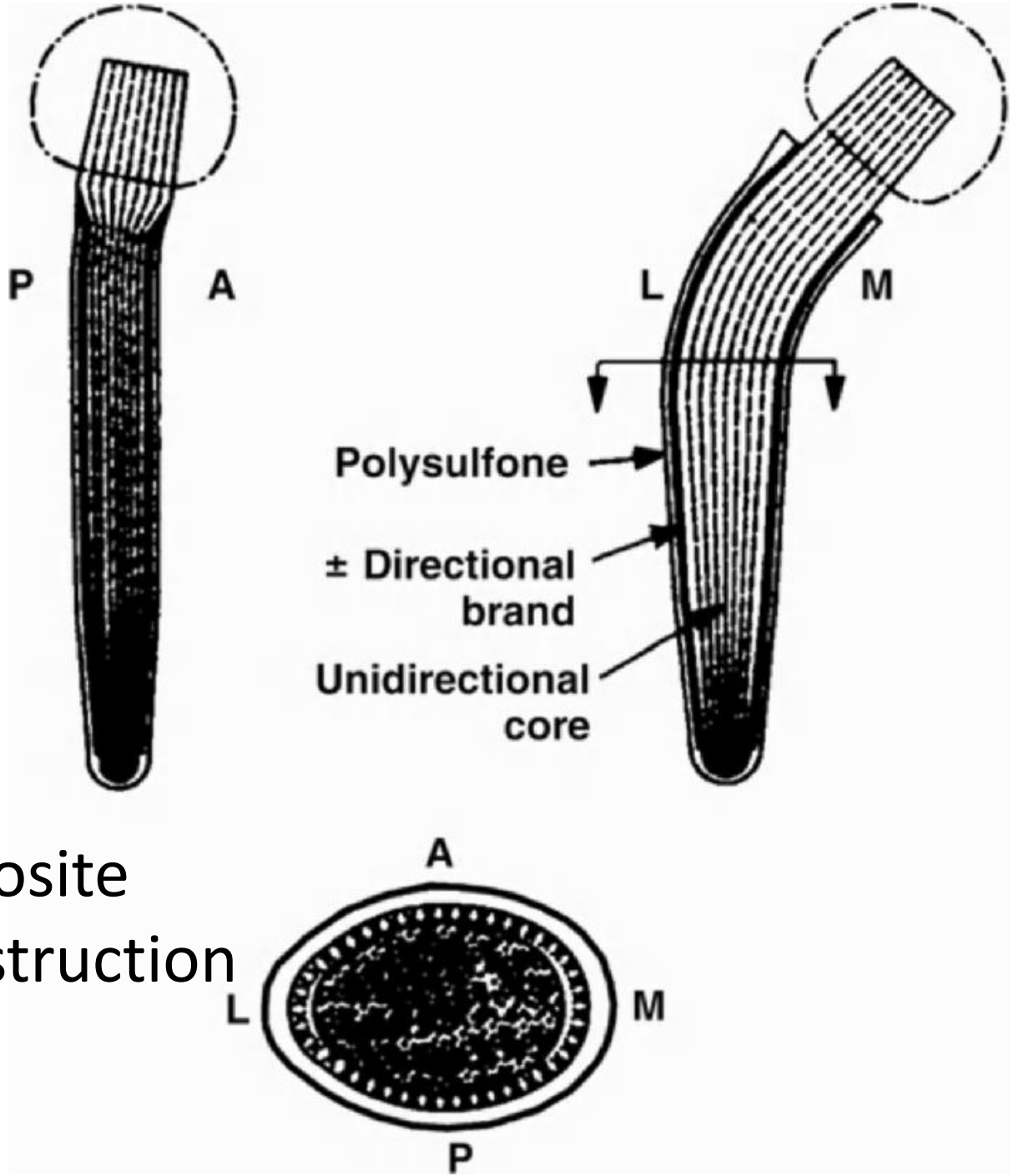


Porous implant



Structure of porous coating for bony ingrowth.

Details of carbon-polysulfone composite femoral stem construction



Knee prostheses with black carbon fiber-reinforced polyethylene tibial components

Soft Tissue Replacement

Requirements

- They should achieve a reasonably close approximation of the physical properties, especially flexibility and texture.
- They should not deteriorate or change properties after implantation over time.
- If materials are designed for degradation, rate and modes of degradation should follow the intended pathway.
- They should not cause adverse tissue reaction-They should be non-carcinogenic, non-toxic, non-allergenic, and non-immunogenic.
- They should be sterilizable.
- They should be low cost.
- Others-feasibility of mass production and aesthetic qualities

Sutures

Types-

- According to the physical integrity

Absorbable (biodegradable) & nonabsorbable.

- According to the source

Natural sutures (catgut, silk, and cotton), and Synthetic sutures (nylon, polyethylene, polypropylene, stainless steel, and tantalum).

- According to the physical form

Monofilament & multifilament

T, Twisted monofilament; M, monofilamene; B, multifilament braid

Table 11-1. Various Types of Sutures Quoted by Roby and Kennedy

Suture type	Generic structure	Major clinical application	Representative Type[a]	Representative product	manufa
Natural materials					
Catgut	Protein	Plain: subcutaneous, rapid-healing	T	Surgical gut	Ethic
		tissues, ophthalmic	T	Surgical Gut	Ethic
		Chromic: Slower-healing tissues	T	Chromic, plain gut	Syne
Silk	Protein	General suturing, ligation	B	Perma-Hand	Ethic
			B	Softsilk	Syne
Synthetic nonabsorbable materials					
Polyester	PET	Heart valves, vascular	B	Ethibond Excel	Ethic
		prostheses, general	B	Surgidac	Syne
			B	Ti-Cron	Syne
			B	Tevdek	Telef
	Polybutester	Plastic, cuticular	M	Novafil	Syne
		Cardiovascular	M	Vascufil	Syne
Polypropylene PP		General, vascular anastomosis	M	Prolene	Ethic
			M	Surgipro	Syne
			M	Surgipro II	Syne
			M	Deklene II	Telef
Polyamide	Nylon 6, 6,6	Skin, microsurgery, tendon	M	Ethilon	Ethic
			M	Monsof	Syne
			M	Dermalon	Syne
		B	Nurolon	Ethicon	
			B	Surgilon	Syne
Stainless steel	CrNiFe alloy	Abdominal and sternal	M, T	Ethisteel	Ethic

Shape Memory effect of Ni-Ti alloy

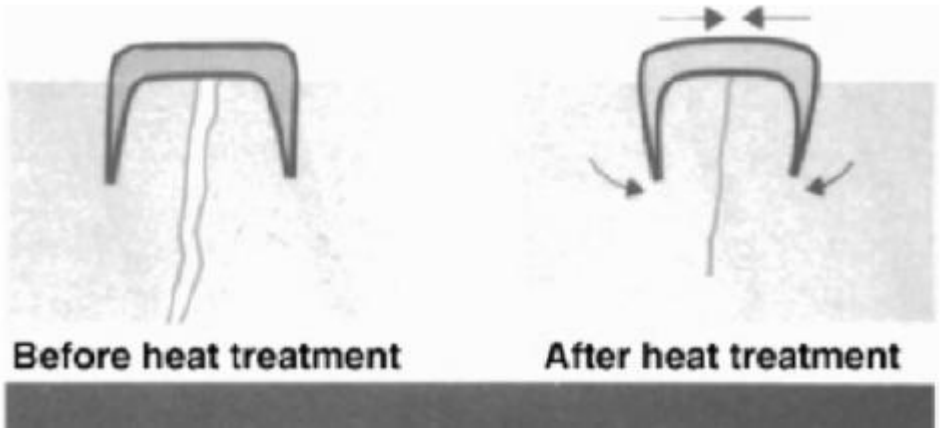
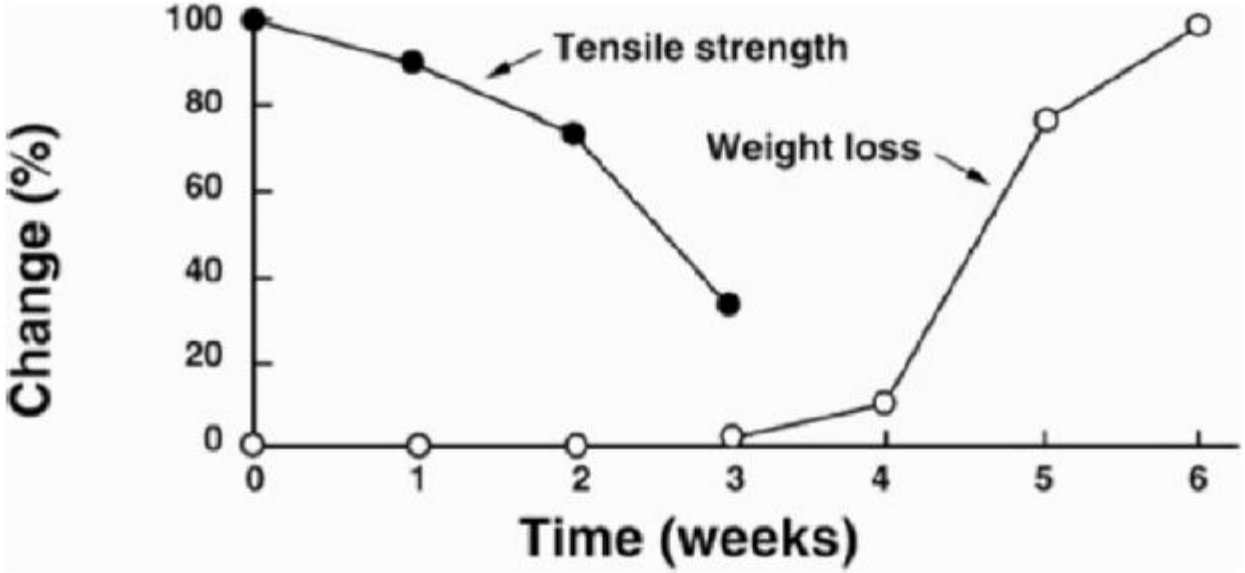


Table 11-2. Polymer Composition of Synthetic Absorbable Sutures

Suture	Block structure	Polymer composition (%)
Multifilament braids		
Dexon	PGA homopolymer	
Vicryl	PGA/PLLA random copolymer	90/10
Polysorb	PGA/PLLA random copolymer	90/10
Panacryl	PGA/PLLA random copolymer	3/97
Monofilaments		
PDS II	PDO homopolymer	–
Maxon	PGA–PTMC/PGA-PGA	100-85/15-100
Monocryl	PGA–PCL/PGA–PGA	100-45/55-100
Biosyn	PGA/PDO–PTMC/PDO–PGA/PDO	92/8-65/35-92/8
Caprosyn	PGAIPCL/PTMC/PLLA random copolymer	70/16/8/5

Absorbable synthetic suture-Vicryl –after implantation



Comparison of absorbability of sutures with time

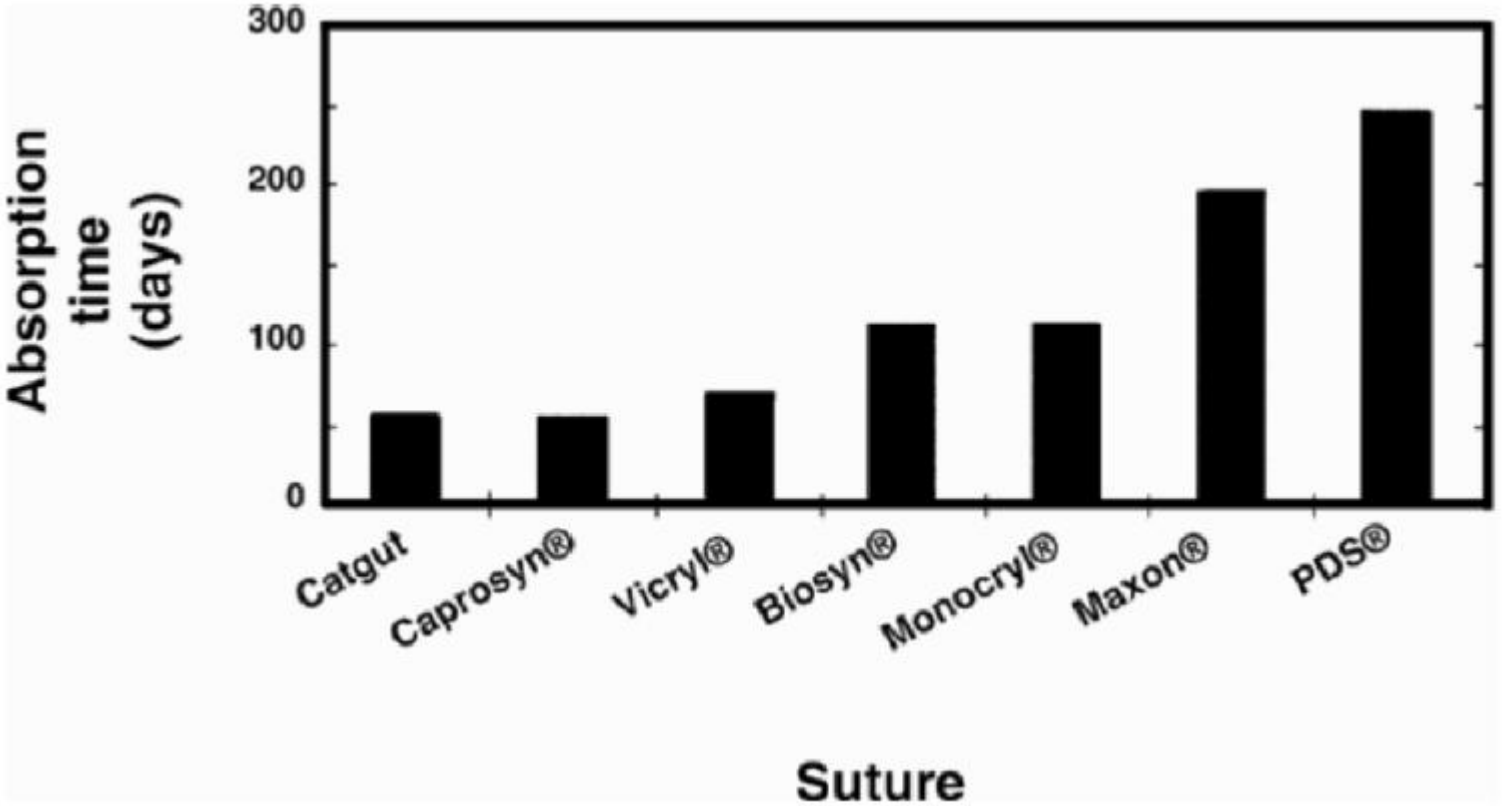


Table 11-3. Minimum Breaking Loads for British-Made Catgut

	Diameter (mm)		Minimum breaking load (lbf)	
Size	Minimum	Maximum	Straight pull	Over knot
7/0	0.025	0.064	0.25	0.125
6/0	0.064	0.113	0.5	0.25
5/0	0.113	0.179	1	0.5
4/0	0.179	0.241	2	1
3/0	0.241	0.318	3	1.5
2/0	0.318	0.406	5	2.5
0	0.406	0.495	7	3.5
1	0.495	0.584	10	5
2	0.584	0.673	13	6.5
3	0.673	0.762	16	8
4	0.762	0.864	20	10
5	0.864	0.978	25	12.5
6	0.978	1.105	30	15
7	1.105	1.219	35	17.5

Fate of suture after implantation

Absorbable

- Biological degradation by enzymes-specific functional groups
- Hydrolysis of synthetic polymers enzymes-specific functional groups

Non-absorbable

Suture material get encapsulated or walled of by fibroblasts

Surgical tapes

Surgical tape or **medical tape** is a type of pressure-sensitive adhesive tape used in medicine and first aid to hold a bandage or other dressing onto a wound.

Features:

- hold firmly onto skin, dressing materials, and underlying layers of tape
- Removed easily without damaging the skin
- Surgical tape is often white because it contains zinc oxide, which is added to help prevent infections
- breathable tapes such as Kinesiology Tape, and other elastic bandages with adhesive are made of cotton, microporous material, such as 3M Micropore, are widely used.
- Some types are commonly used in sports to add a non-slip wrapping to things which must be gripped, such as tennis racquets, and hockey and lacrosse sticks, because of their rough texture and removability leaving little residue.

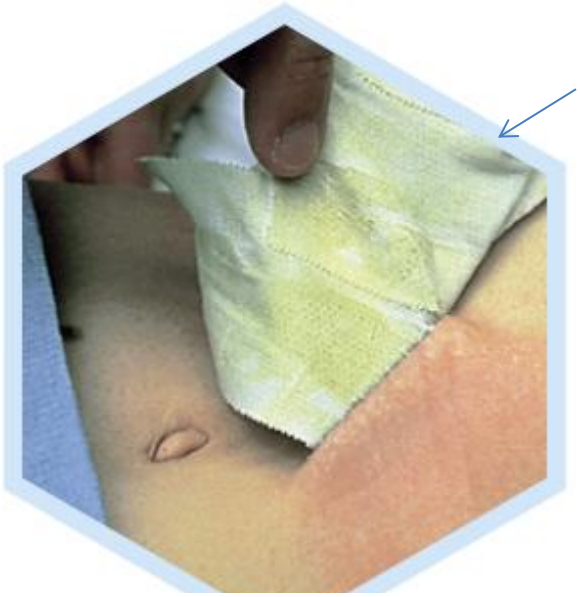
Pressure sensitive adhesive in Surgical tapes

- natural rubber adhesives,
- synthetic rubber adhesives,
- acrylic adhesives

Typical applications;

single-coated tapes in wound care dressings, surgical tapes and electrodes,

double coated tapes and transfer adhesives diagnostic test strips, ostomy devices, surgical drapes, advanced wound care dressings and other

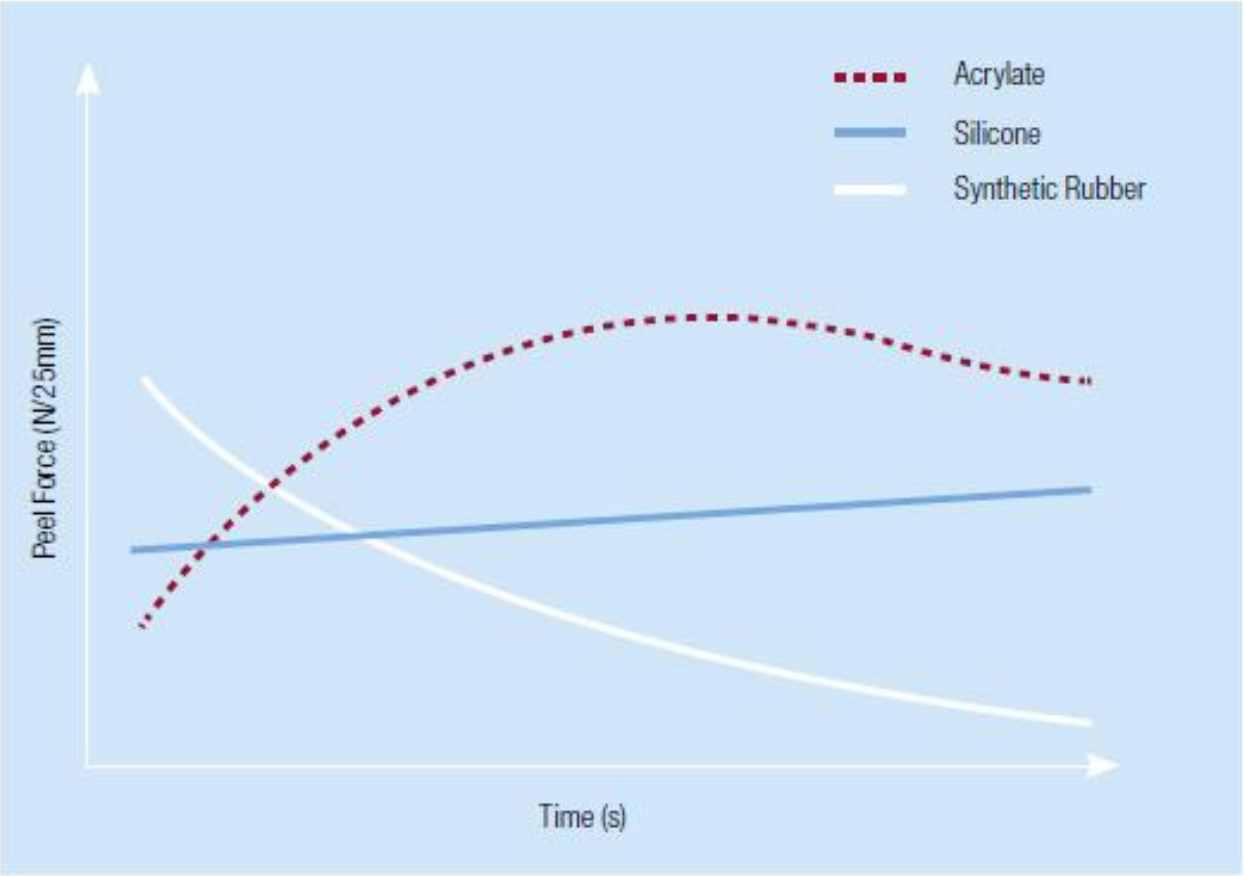


Skin Trauma due to rubber based adhesive

Paper backing PSA

PU backed PSA
Breathable

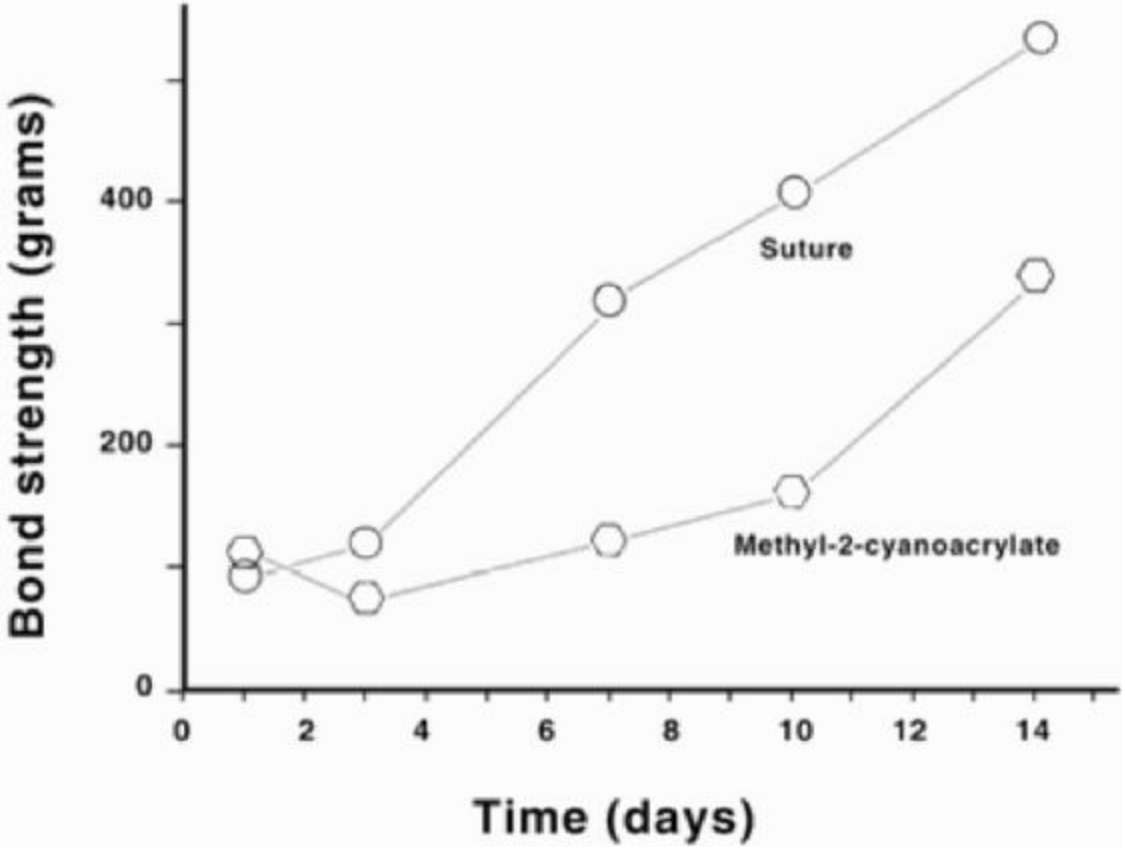
Comparison of three types of PSA



Ligament, Cartilage, tendons

- Ligament-connective tissue that joins bone to bone-strong, elastic, fibrous
- Tendons-connective tissue that joins bone to muscles-strong, elastic, fibrous
- Cartilage-connective tissue that acts as soft cushion on bone-strong, elastic, fibrous

Tissue Adhesives



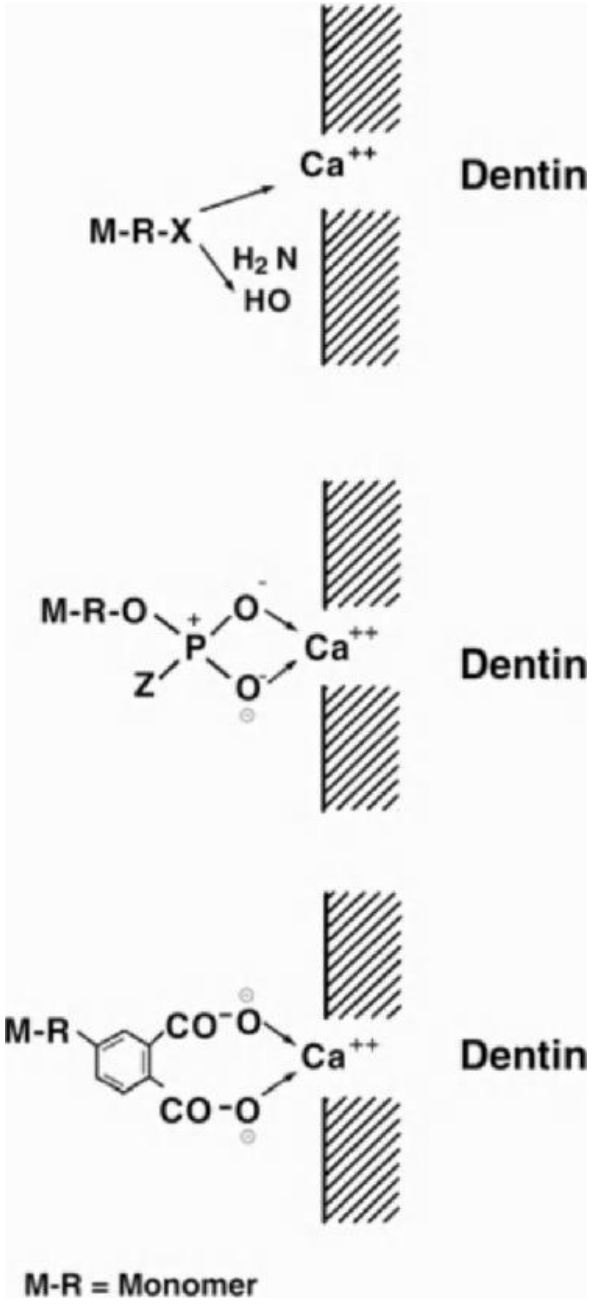
Main Strength depends on-

- Covalent bonding
- Thickness,
- porosity
- Flexibility
- Rate of degradation

Table 11-4. Mechanical Properties of Dental Cements and Sealants

Materials	Compressive strength (MPa)	tensile strength (MPa)	Modulus (GPa)	Toughness K_{IC} (MPa $m^{1/2}$)
Zinc phosphate	80–100	5–7	13	~0.2
Zinc polycarboxylate	55–85	8–12	5–6	0.4–0.5
Glass ionomer	70–200	6–7	7–8	0.3–0.4
Resin sealant unfilled	90–100	20–25	2	0.3–0.4
Resin sealant filled	150	30	5	–
Resin cement	100–200	30–40	4–6	–
Composite resin filling material	350–400	45–70	15–20	1.6

Materials indicate the nature of fillers and other additives(tackifiers, sealants etc.)



Fixation of dental resin monomers with adhesive through Ca^{+2}

Percutaneous Devices

Skin implant

- Problems-

➢ Attachment is not permanent

➢ Downgrowth and/or overgrowth of epithelium around the device

➢ Any opening may cause bacterial infection

Factors and variables concerned

End-use factors

- a. Transmission of information: biopotentials, temperature, pressure, blood
- flow rate, etc.
- b. Energy: electrical and electromagnetic stimulation, power for heart assist
- devices, cochlear implants, etc.
- c. Matter: cannula for kidney dialysis and blood infusion or exchange, etc.

Engineering factors

- a. Materials selection: polymers, ceramics, metals, and composites.
- b. Design variations: button, tube with and without skirt, porous or smooth
- surface, etc.
- c. Mechanical stresses: soft and hard interface, porous or smooth interface.

Biological factors

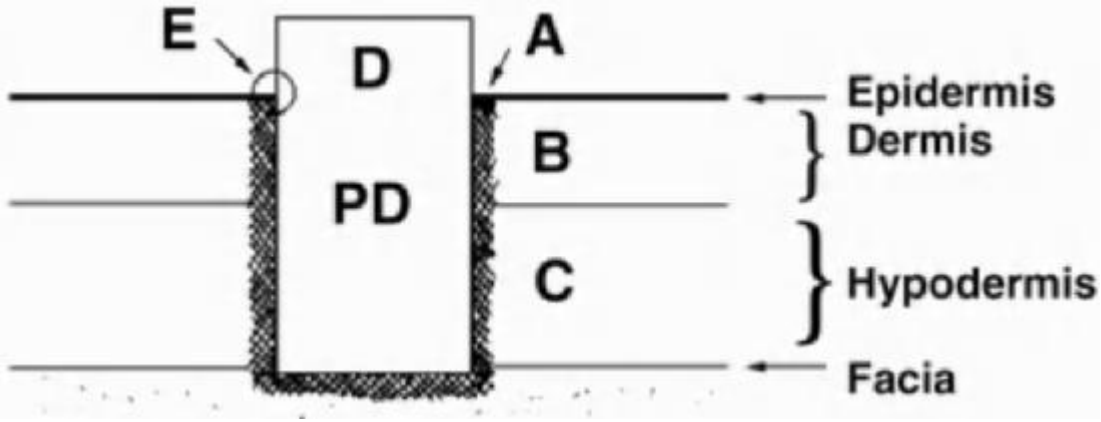
- a. Implant host: man, dog,rabbit, sheep, etc.
- b. Implant location: abdominal, dorsal, forearm, etc.

Human factors

- a. Postsurgical care.
- b. Implantation technique.
- c. Aesthetic outlook.

Cross-sectional Image of PD-skin interface

Figure 1



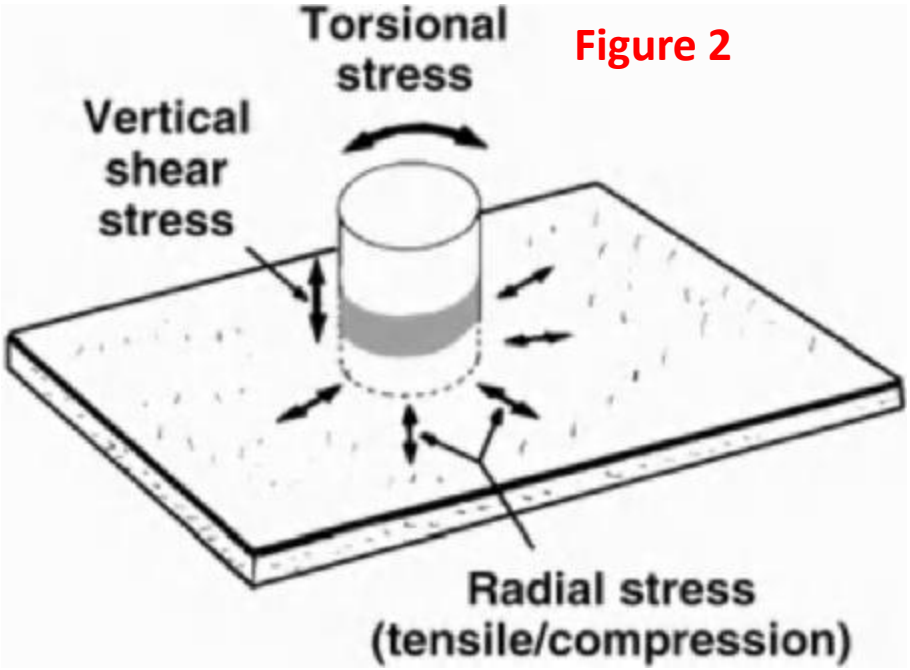


Figure 2

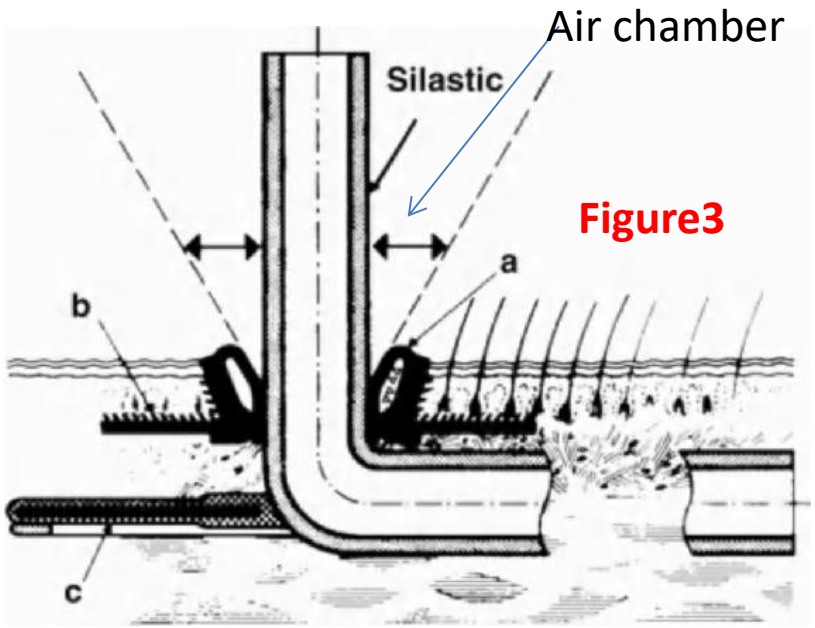
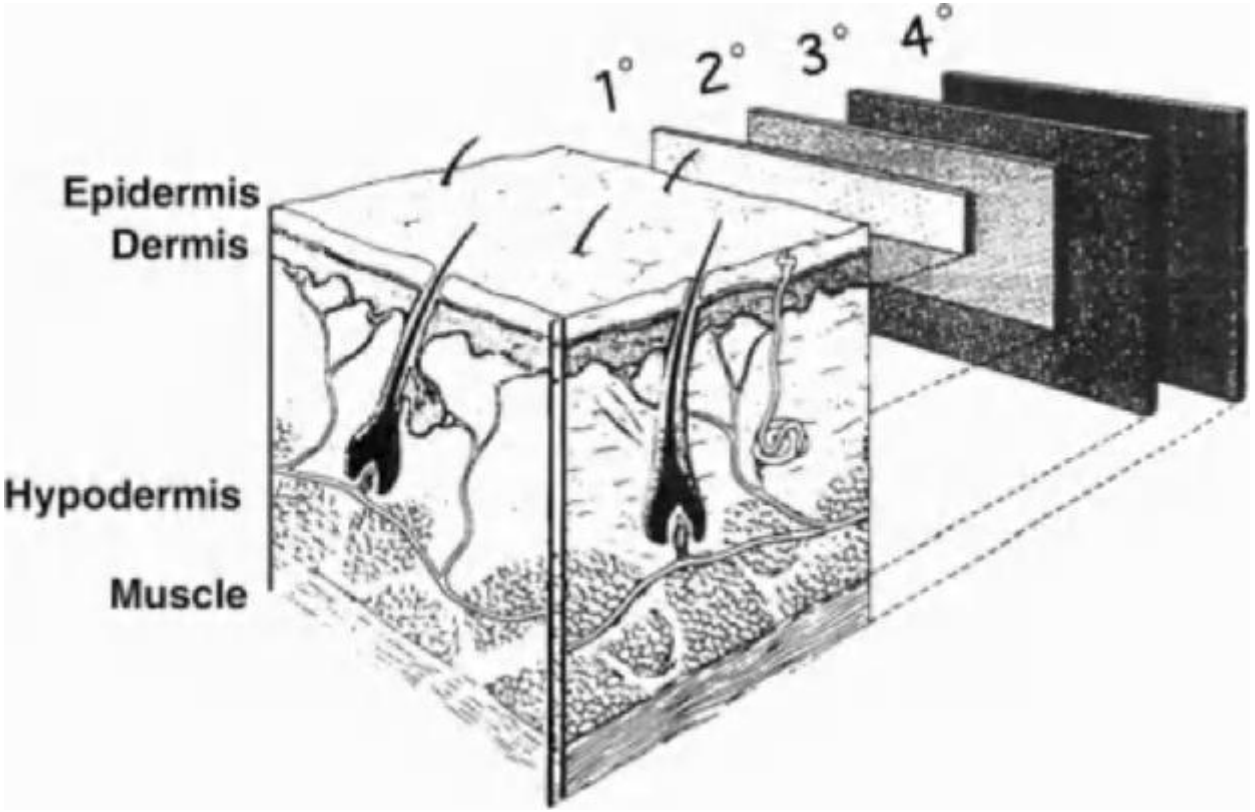


Figure3

Artificial Skins and Burn Dressing

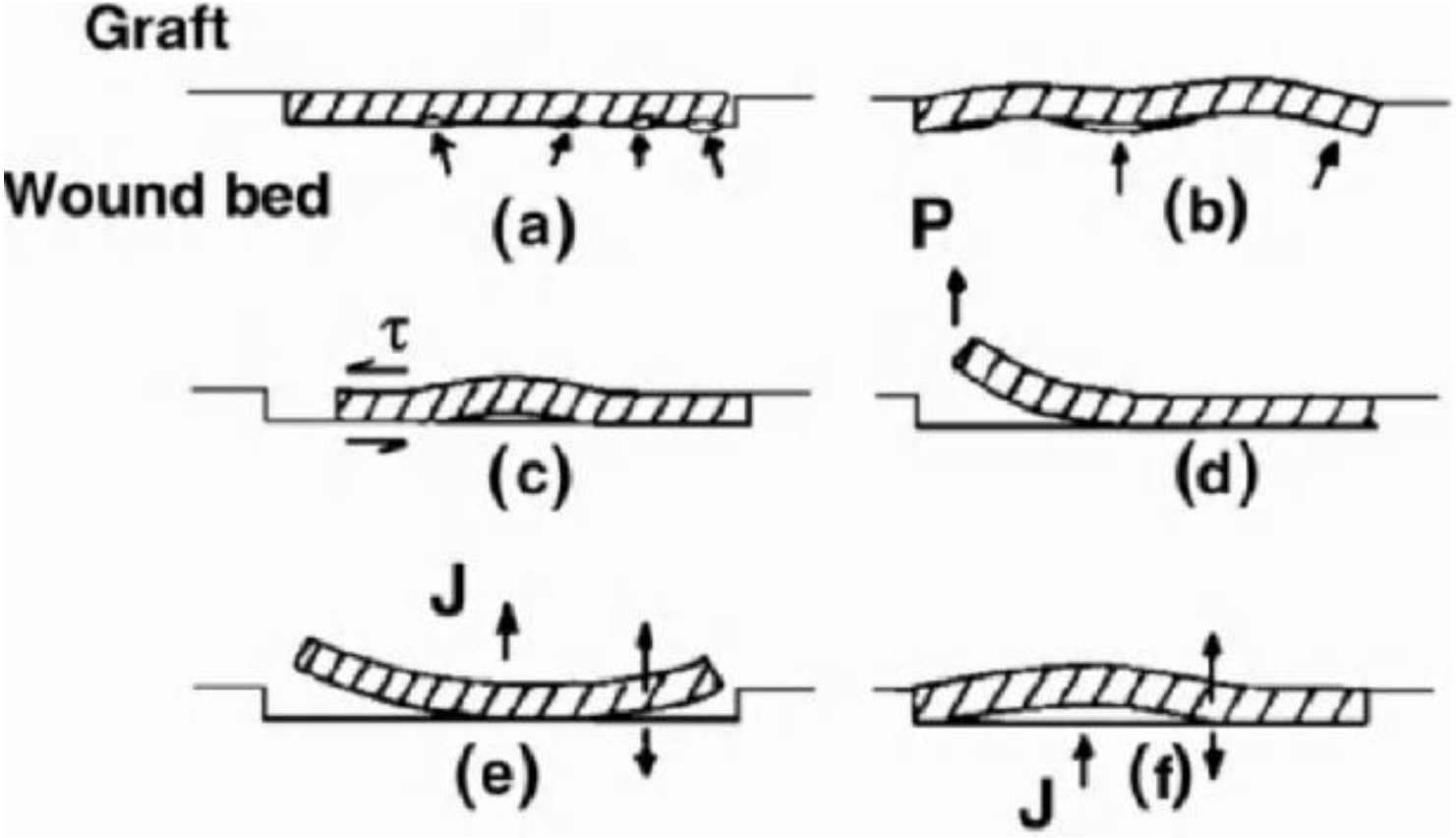


Materials Used for temporary and permanent Skin transplantation

Membrane	Selected characteristics
Temporary	
Porcine xenograft	Adheres to coagulum, excellent pain control
Biobrane[a]	Bilaminate, fibrovascular ingrowth into inner layer
Split-thickness allograft	Vascularizes and provides durable temporary closure
Various semipermeable membranes	Provides vapor and bacterial barrier
Various hydrocolloid dressings	Provides vapor and bacterial barrier, absorbs exudate
Various impregnated gauzes	Provides barrier while allowing drainage
Allogeneic dressings	Provides temporary cover while supplementing growth factors
Permanent	
Epicel[b]	Provides autologous epithelial layer
Integra[c]	Provides scaffold for neodermis, requires delayed thin autograft grafting
AlloDermd	Consists of cell-free human dermal scaffold, requires immediate thin autograft

[a]Mylan Laboratories, Inc. [b]Genzyme Biosurgery Inc., Cambridge, MA. [c]Integra Life Sciences Corporation, Plainsboro, NJ. [d]LifeCell Inc.. Branchburg, NJ.

Design requirements and schematic representation of skin implants



Ear Implant

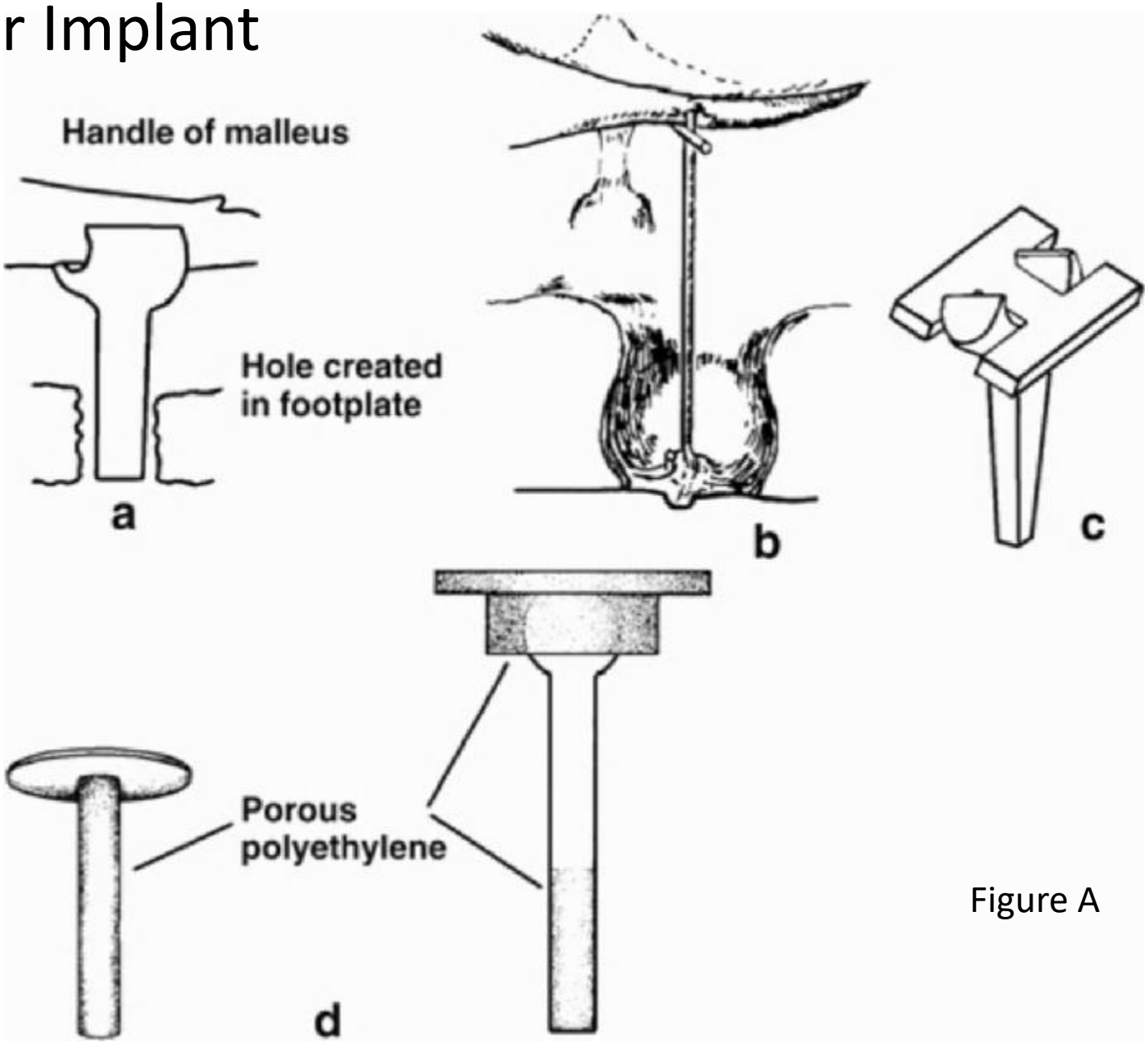


Figure A

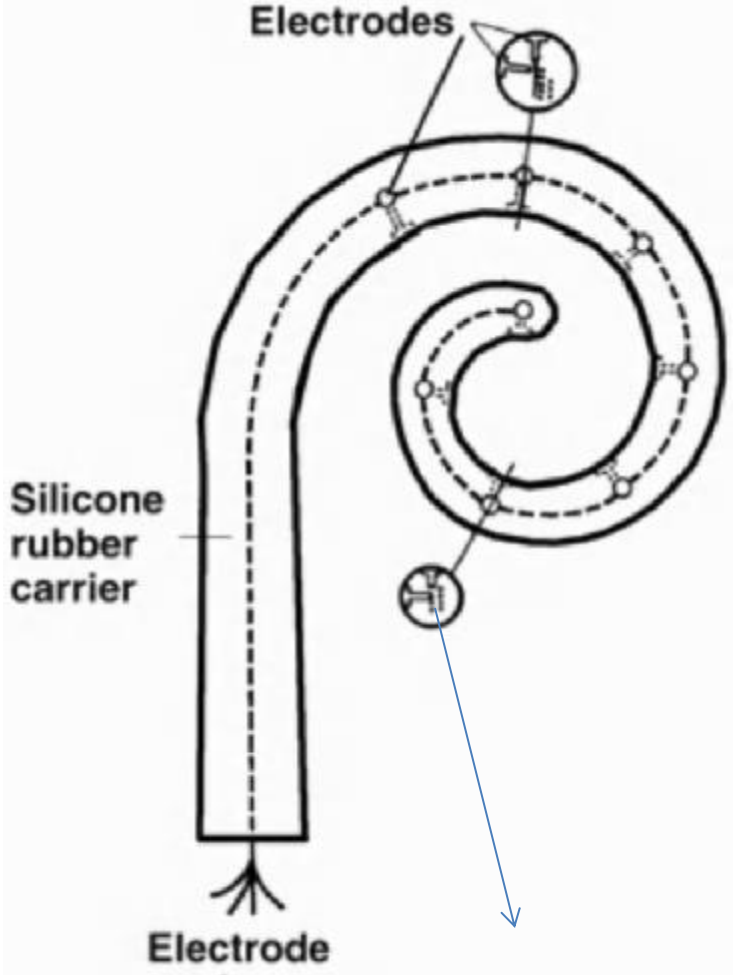
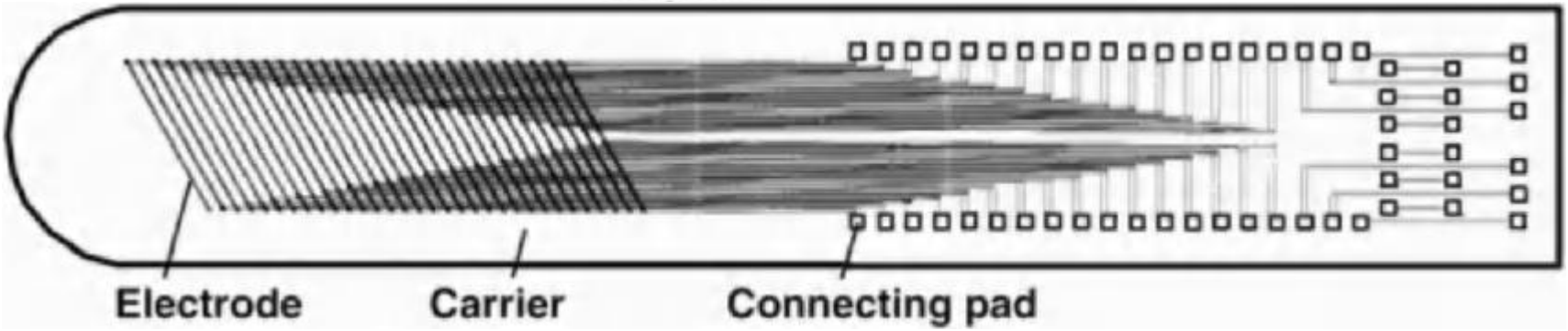

Electrodes
Silicone rubber carrier
Electrode

Figure B


Electrode
Carrier
Connecting pad

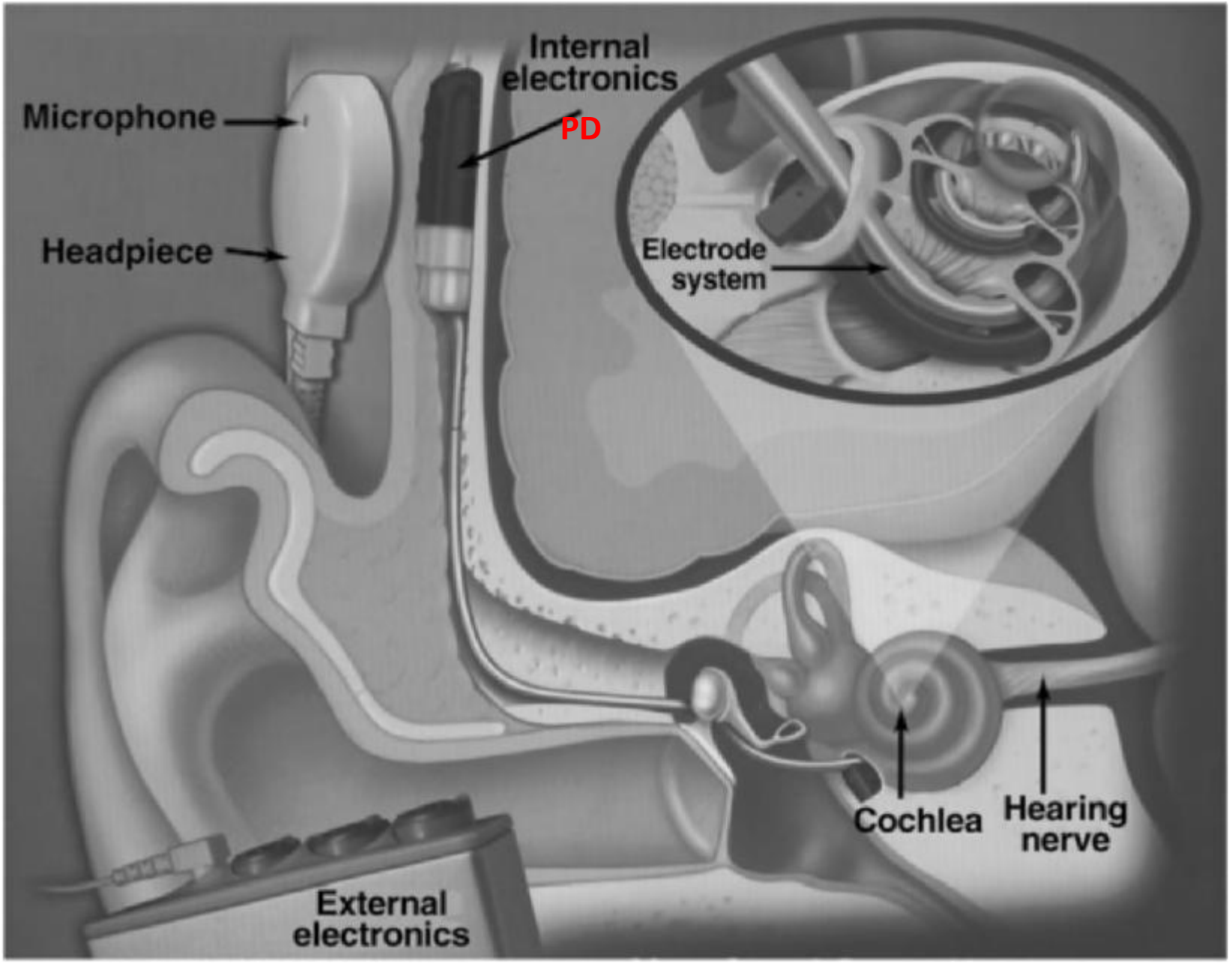

Internal
electronics
PD
Microphone
Headpiece
Electrode
system
Cochlea
Hearing
nerve
External
electronics

Figure C

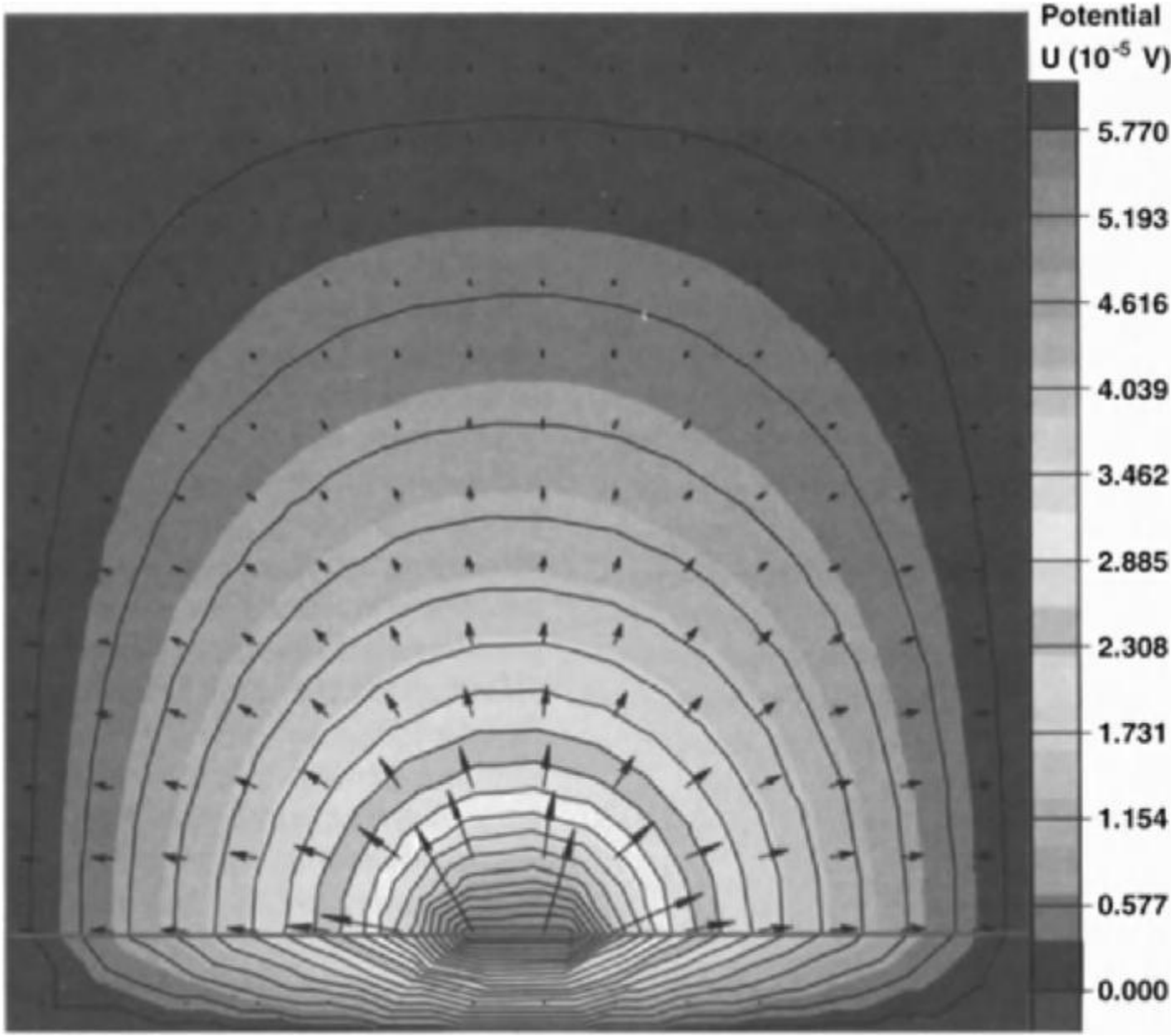

Potential
U (10^-5 V)
5.770
5.193
4.616
4.039
3.462
2.885
2.308
1.731
1.154
0.577
0.000

Figure D